MEETING

STATE OF CALIFORNIA

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

GREEN RIBBON SCIENCE PANEL

Calepa Headquarters Building Conference Room 550, 5TH FLOOR

1001 I STREET

SACRAMENTO, CALIFORNIA 95814

WEDNESDAY, APRIL 24, 2019 8:00 A.M.

Reported by: Peter Petty

APPEARANCES

PANEL MEMBERS PRESENT

Kelly D. Moran, Ph.D., Co-Chair

Arthur Fong, Ph.D., Co-Chair

Ann Blake, Ph.D.

Michael Caringello, MBA

Elaine Cohen-Hubal, PhD

Jack Linard, Ph.D.

Rebecca Sutton, Ph.D.

Ken Zarker

DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC)

Meredith Williams, Ph.D., Acting Director

Karl Palmer, Acting Deputy Director

Kerry Rasmussen

Xiaoying Zhou

Anne Cooper Doherty

Tony Luan

Michelle Romero-Fishback

Kelly Grant

Anna Gross

PRESENTERS/SPEAKERS

Jared Blumenfeld, Secretary, Cal/EPA

Xiaoying Zhou, Ph.D., P.E., Senior Hazardous Substances Engineer,

Safer Products and Workplaces Program

Dr. Margaret Whittaker of ToxServices LLC

PUBLIC COMMENT

Kraig Kurucz, Lockheed Martin Space Systems

Brian Penttila, Washington State Department of Ecology (Statement read into the record.)

AGENDA

Morn		age
1.	Welcome, Opening Remarks and Agenda Review	5
2.	Public Comment	16
3.	Presentation on Alternatives Analysis Review Process and Discussion	
	• SCP Alternatives Analysis Review: Xiaoying Zhou	20
	 Tips and Tricks for Review of AAs 	36
	Dr. Margaret Whittaker of ToxServices LLC will present on her lessons learned in evaluating alternatives assessments. Dr. Whittaker and the Panel will discuss recommendations for DTSC in their upcoming evaluation of the first Alternatives Analyses submitted per the SCP regulations. - Pertinent Sections of the Safer Consumer Product Regulations and FSOR - Guest Speaker Profile for Dr. Margaret Whittaker - Two Stage AA Overview - Priority Product Profile - Paint or Varnish Stripper - Priority Product Profile - SPF with Unreact MDI	he n
4.	Conclude and Adjourn 1	36
Adjo	urnment 1	42
Tran	scriber's Certificate 1	43

1 PROCEEDINGS

- 2 8:03 A.M.
- MS. RASMUSSEN: Good morning everyone and
- 4 welcome to day two of DTSC's Green Science Panel Meeting.
- 5 My name is Kerry Rasmussen and I'm DTSC's or Department
- 6 of Toxic Substances' Public Participation Representative.
- 7 On behalf of the Department I'd like to thank you all for
- 8 taking the time to be here today.
- 9 Let me take this moment to announce that in
- 10 addition to those of us here in the room today the public
- 11 is following us via the webcast. If you are tuning in to
- 12 the discussion via the webcast, and you'd like to provide
- 13 input, please email your questions and comments to
- 14 SaferConsumerProducts@dtsc.ca.gov.
- Today's meeting is also being recorded and
- 16 transcripts will be posted to the DTSC's public website
- 17 once they are made available to the Department.
- 18 A short evacuation announcement. In case of
- 19 emergency please notice the two exit doors are over here
- 20 with the lit exit signs above them. We hope that's not
- 21 the case, but if we do need to evacuate please bring your
- 22 valuables with you. Our staff will work to guide you to
- 23 the nearest exit. If we need to leave the floor, please
- 24 do not use the elevators, use the stairways instead. And
- 25 if we need to leave the building, we'll be evacuating to

- 1 the Cesar Chavez Park across the street.
- 2 A few housekeeping details. The restrooms, the
- 3 women's restroom is all the way down either hallway. The
- 4 men's restroom is directly outside the door to the left.
- 5 The water fountains are near the women's restroom.
- 6 Public comments. We will be providing an
- 7 opportunity for public comments later this morning. We
- $8\,$ ask that anyone who is interested in providing a public
- 9 comment please hand your public comment card in when you
- 10 are ready. For those of you who are tuning in remotely
- 11 you may email your comment to
- 12 SaferConsumerProducts@dtsc.ca.gov and it will be read
- 13 aloud.
- 14 Finally, I want to announce that all attendees
- 15 at today's Green Ribbon Science Panel, you are subject to
- 16 the Bagley-Keene Open Meeting Act to preserve public
- 17 transparency and the panel's discussion and decisions.
- 18 I'd now like to turn it over to Dr. Meredith
- 19 Williams, Acting Director of the Department of Toxic
- 20 Substances Control for the opening remarks.
- 21 ACTING DIRECTOR WILLIAMS: Thank you, Kerry.
- 22 And as you can see, I've brought someone with
- 23 me. And therefore I really don't intend -- nope. (Off
- 24 mic colloquy, laughter.) And I brought the Secretary,
- 25 this is Secretary Jared Blumenfeld as many of you already

- 1 know. I know a lot of you have interacted with him in
- 2 his role at either the San Francisco Department of the
- 3 Environment or USEPA Region IX as Administrator there and
- 4 we are incredibly fortunate to have him at the helm of
- 5 CalEPA.
- 6 Number one, to have someone walk in with that
- 7 wealth of experience has been tremendously beneficial.
- 8 And I, from the most the selfish view possible, it's been
- 9 fantastic just because he came in with a deep knowledge
- $10\,$ of the Department, a deep knowledge of what our
- 11 challenges are, and what our opportunities are. And I
- 12 think it's fair to say that Safer Consumer Products is
- 13 one of those opportunities.
- 14 And he was kind enough to take a few minutes
- 15 before he heads downstairs to the throngs of kids to
- 16 inspire them about Earth Day and environmental
- 17 protection. But he has a few minutes, so I thought he
- 18 could share a few thoughts. So thank you, Jared, for
- 19 making the time for us.
- 20 SECRETARY BLUMENFELD: Of course. And thanks
- 21 to all of you, thanks particularly to the Co-Chairs, but
- 22 all the members of the Green Ribbon Panel and to everyone
- 23 in the room.
- Just to give you a sense, I think, of how
- 25 important this panel is to me and to the Administration

- 1 when you think about kind of where we are in 2019 as a
- 2 country or as a state, the preeminence and importance of
- 3 putting science first is something I think California
- 4 represents. Often, science as an institution has been
- 5 eroded. The use of science in policy-making has often
- 6 been short-circuited. So to have a Green Ribbon Panel
- 7 that really is focusing on a different direction is
- 8 incredibly important, just incredibly important. And
- 9 incredibly important to me, DTSC, CalEPA and the
- 10 Governor. So I really want to thank you for, I know
- 11 often that you come a long way for these meetings and I
- 12 just want to let you know that we really thank you and
- 13 acknowledge the work that you do.
- When it comes to safer consumer products, we
- 15 all assume that all of our consumer products are safe.
- 16 So I think we all start with this misguided sense of
- 17 safety, and even probably a sense of what we can attain
- 18 in terms of safety.
- 19 I spent a lot of time when I was in San
- 20 Francisco and Gavin Newsom was the Mayor thinking about
- 21 procurement; thinking about how to come up with a better
- 22 way of purchasing; how cities, states, government can
- 23 play a role to lead the way to show what can be done when
- 24 it comes to safer consumer products. We have a long way
- 25 to go, a very long way to go. And part of that is really

- 1 showing people what's possible, which is what you do.
- 2 Because I think people, you know, as our former
- 3 Governor and President Reagan said, "We have to trust,
- 4 but verify." People want to trust in a product, but you
- 5 help them verify that the process that we go through has
- 6 integrity. And I think integrity is something that we
- 7 all need to bolster in a time when people have lost faith
- 8 in government, have lost faith in institutions that they
- 9 used to be able to rely upon.
- 10 So explaining as you do, "This is how we're
- 11 thinking about an issue. This is how we're going to move
- 12 forward in discussions with manufacturers. This is how
- 13 we think about Alternatives Analysis," really does shift
- 14 that whole perspective about how we look at risk as an
- 15 agency.
- 16 And certainly, I was having a discussion
- 17 yesterday with folks about how pesticides are evaluated
- 18 and how we do a risk assessment and risk management. And
- 19 really the model that you are bringing to the table is
- 20 the one that I think we need to replicate. How do we
- 21 think about alternative analysis? How do we push
- 22 alternatives so that they're viable, quicker in the
- 23 marketplace? How do we, in some cases, cut the
- 24 regulatory bureaucracy and red tape for things that
- 25 plainly don't need certain risk thresholds.

- 1 So I really think that what you're doing has an
- 2 expansive role outside this room and outside these
- 3 particular issues. And hopefully it will be a model for
- 4 many, many others as they engage in a similar process, so
- 5 mainly just thank you.
- 6 And as much as Meredith said kind words about
- 7 me, I just want to apologize for stealing her from you.
- 8 You have Karl, but I have Meredith. (Laughter.) So I'm
- 9 grateful that Meredith accepted the offer to come on and
- 10 really help shape the agency. And I think much of what
- 11 she's doing is very much informed by the process and
- 12 engagement that she's had with you. So she's awesome, as
- 13 you know, and I'm really thankful that I get to work with
- 14 her every day. So thank you.
- 15 And I don't know if there's any questions? I'm
- 16 happy to answer any. You've already got pictures?
- 17 (Laughter.)
- 18 Kelly?
- 19 PANEL CO-CHAIR MORAN: What's your vision for
- 20 the program? What's your vision, going forward for Safer
- 21 Consumer Products?
- 22 SECRETARY BLUMENFELD: Well, I think there's
- 23 opportunities as we saw in the analysis that was done and
- 24 released a few months ago, just to think about how we
- 25 streamline. And I think that there's always

- 1 opportunities to kind of take those -- I think it was a
- 2 constructive criticism -- and really look at are there
- 3 opportunities to think about how we accelerate some of
- 4 the work?
- I think the challenge that you have is that
- 6 people want what you're doing and want it more and
- 7 quicker. And often that is hard to achieve with the
- 8 staff and resources that we have. And so really thinking
- 9 about what does the scale of this project look like ten
- 10 years from now? How do we meet the demand for this
- 11 exercise? Because even with the range, I love reading
- 12 the range online of how many chemicals are in production
- 13 on the planet. It goes from 80,000 and then there's all
- 14 this criticism about it can't possibly be 80,000. It's
- 15 80 --
- 16 ACTING DIRECTOR WILLIAMS: It's 43.
- 17 SECRETARY BLUMENFELD: -- you're right, 43.
- 18 ACTING DIRECTOR WILLIAMS: It's 43,000.
- 19 SECRETARY BLUMENFELD: But then there's some
- 20 others that say it's like 24,000 and then 7. But my --
- 21 even if it was 2,000 is my point, that's a lot. Like
- 22 80,000 is like -- even 43; I mean, it's beyond anyone's
- 23 comprehension. No one in their daily lives can
- 24 comprehend that many chemicals that are out there. And
- 25 so the pace of producing chemicals obviously outstrips

- 1 our ability to analyze them and understand how to shape
- 2 that policy.
- 3 So I mean I think the evolution is really to
- 4 fulfill your promise, which I think you're doing. But
- 5 there's just a lot more appetite for more and faster, so
- 6 that's what I kind of got of it. So, that isn't -- and
- 7 explaining that science often doesn't go quickly
- 8 sometimes it frustrates people. And that's sometimes why
- 9 they want to jump ahead of it. "Like why do we have to
- 10 wait for the science? Let's just get it," whatever "it"
- 11 is, "done." So explaining that it takes time to do
- 12 rigorous peer review science and it takes time to analyze
- 13 it and the benefits of doing that are that at the end
- 14 it's incontrovertible or at least it's a lot more
- 15 supportable.
- So I think those are the kind of dynamic
- 17 tensions that you are going to have to navigate and think
- 18 about.
- 19 Yeah, one of the first things we did in San
- 20 Francisco is write the opening to our municipal code as a
- 21 precautionary principle. And thinking about how we ask
- 22 questions differently, so rather than asking how much
- 23 risk is allowable ask whether that product is actually
- 24 necessary. And whether alternatives exist, really, is at
- 25 the heart of what you are doing. But reframing some of

- 1 the questions around risk assessment and management and
- 2 thinking about how that could apply in context further
- 3 afield than consumer products, I think is something that
- 4 I'd be interested in talking with you about.
- 5 PANEL CO-CHAIR FONG: So besides doing more and
- 6 doing it faster, do you see this program as a possible
- 7 driver for economic development that the original Green
- 8 Chemistry Initiative was thinking?
- 9 SECRETARY BLUMENFELD: Absolutely. I mean, I
- 10 think the reason that California's GDP is way ahead of
- 11 the rest of the nation's when you look at a state-by-
- 12 state basis is because of their innovation and the desire
- 13 to not rest on our laurels where we are now. And these
- 14 kind of forward-thinking whether it's a low-carbon fuel
- 15 standard or thinking about how we build transit-oriented
- 16 development communities or thinking about environmental
- 17 justice and how we deal with trade and goods movement,
- 18 all those are opportunities for economic development.
- 19 And we see that they are.
- 20 So in every business you're going to have
- 21 status-quo products and businesses that aren't able to
- 22 catch up. And then in the case, one early example in
- 23 California was the catalytic converter. You know, the
- 24 people that sold catalytic converters, that business did
- 25 well. The company that sold internal-combustion engine

- 1 with no controls, they didn't do so well.
- 2 So, often if we only look at one part of the
- 3 picture the folks that are making methyl ethyl death,
- 4 they may not do so well. But they may understand and see
- 5 the writing on the wall from what you're doing and say,
- 6 "It's time for us to change and transform," which you see
- 7 in a lot of large fossil-fuel companies are now switching
- 8 to renewables, switching to energy efficiency.
- 9 So I think what you're doing is sending strong-
- 10 market signals about the direction of the California
- 11 economy. And with 40 million consumers and obviously
- 12 manufacturers that don't want to make things just for the
- 13 California market, you around this table have an outsized
- 14 influence to be in a position of helping push innovators,
- 15 push more businesses that have a product that now has a
- 16 niche because of you. So absolutely this is a big
- 17 economic tradeoff, maybe not quite as big as Apple, but
- 18 one day.
- 19 PANEL CO-CHAIR FONG: Well, we're not going
- 20 anywhere, so.
- 21 SECRETARY BLUMENFELD: Excellent. I know,
- 22 because you've got like a round building you can't go
- 23 anywhere. That's why it's called the infinity loop,
- 24 right?
- 25 PANEL CO-CHAIR FONG: That's the old campus.

- 1 The new camp is Apple Park.
- 2 SECRETARY BLUMENFELD: Okay. It's been bred
- 3 into you. I like that. You work with Lisa?
- 4 PANEL CO-CHAIR FONG: Ah yes, it's a pleasure
- 5 in working with Lisa.
- 6 SECRETARY BLUMENFELD: Yeah, she's cool. Lisa
- $7\,$ Jackson was my boss at EPA and now is a boss at Apple.
- 8 Cool.
- 9 PANEL CO-CHAIR FONG: Thank you.
- 10 ACTING DIRECTOR WILLIAMS: Thank you.
- 11 SECRETARY BLUMENFELD: Now we go to the kids.
- 12 (Laughter.)
- 13 ACTING DIRECTOR WILLIAMS: I just got to see of them.
- 14 Thanks Jared.
- 15 SECRETARY BLUMENFELD: Thank you.
- 16 PANEL CO-CHAIR FONG: Thank you and the kids.
- 17 So at this point let's continue with our
- 18 meeting, so let me just go over the agenda for this
- 19 morning. So we'll begin today with a public comment
- 20 period. After which we'll spend actually much of the
- 21 morning discussing the programs review of submitted
- 22 Alternatives Analysis. Xiaoying Zhou from the program
- 23 will give us an overview of the program's efforts to
- 24 prepare to receive and review the AAs this summer.
- 25 And then Dr. Whittaker from ToxServices will

- 1 then give us a presentation about her experience
- 2 reviewing AAs and advice that she thinks would be helpful
- 3 for DTSC.
- 4 We'll follow these presentations with, again,
- 5 quite a bit of time this morning for a panel discussion.
- 6 And if time allows, we'll just come back to some of the
- 7 topics that we touched on yesterday that you think should
- 8 require additional thought and discussion.
- 9 So, at this point public comments.
- 10 MS. RASMUSSEN: Before today's panel discussion
- 11 we will once again be taking public comments. If there
- 12 are webinar participants who wish to comment at today's
- 13 meeting please email your comments to
- 14 SaferConsumerProducts@dtsc.ca.gov and it will be read
- 15 aloud. Comments submitted remotely will be read to the
- 16 panel after we hear comments from those in the room.
- 17 The public is reminded that today's comments
- 18 are directed to the Green Ribbon Science Panel and on
- 19 agenda topics; that is, the materials that were presented
- 20 by the panel. Public comments directed to DTSC are not
- 21 appropriate at this meeting.
- 22 Please note it that the panel is not able to
- 23 respond to comments or answer any questions as this is a
- 24 working meeting. If you have not signed up to comment
- 25 you may do so at this time. Staff have commenter cards

- 1 for you to indicate that you wish to comment. Based on
- 2 the number of comments we may need to limit the time.
- 3 So we have one so far from those in the room.
- 4 Does anyone else have one here in the room? Okay.
- Now we have Kraig Kurucz from Lockheed Martin
- 6 Space coming up to give a comment.
- 7 MR. KURUCZ: Good morning members of the panel
- 8 and DTSC staff. I'm Kraig Kurucz. I'm from Lockheed
- 9 Martin Space and I'm coming to make a comment just to
- 10 explain a situation. We have a specific use for
- 11 methylene chloride strippers. And we are hopeful that
- 12 someone will request that there be an AA done on this
- 13 topic. But since it would require the vendors, and we
- 14 buy five gallons a year, we're not really sure if they
- 15 will come in and do that.
- 16 Our particular use is always done wearing a
- 17 specific PPE for methylene chloride and in a paint booth
- 18 that has excellent ventilation and is downdraft and is
- 19 approximately the size of this room. So we really
- 20 delimit the exposure. We do support removing it from
- 21 regular consumer activities, because of the problems of
- 22 people that don't have that kind of equipment or
- 23 supervision, so we certainly understand that.
- Like I said we use somewhere between two and
- 25 ten gallons a year always on rework, either something

- 1 brought back to us from the field if it's something that
- 2 maybe the military customer was using. Or as part of a
- 3 satellite where something failed tests. We do a lot of
- 4 testing before launch, because we can't go out there and
- 5 repair things. So if a bond is suspicious or some
- 6 coating, anti-reflective coating or something like that
- 7 is maybe going to flake off later, they will remove that
- 8 and make a repair.
- 9 These coatings are very efficient. They're
- 10 thixotropic, so they're like a gel and they stay on. I
- 11 checked on the last use. They worked on nine satellite
- 12 parts that they had to recoat, and they used 20 mls,
- 13 because they do stay right there. So we don't have to
- 14 splash it on or anything like that.
- We do use alternatives when it's available. It
- 16 just depends on the type of hardware. So some of our
- 17 hardware is made out of what they call honeycomb core, so
- 18 it's expanded aluminum and it looks like honeycomb. And
- 19 all we have to bond it to a carbon sheet on the top and
- 20 carbon sheet on the bottom, or maybe titanium, would be
- 21 just those knife edges. So there's not a lot there, so
- 22 the adhesives need to work really well. And then we test
- 23 it and see if it pulls apart and so forth and if it does
- 24 then we have to redo that work.
- 25 The key thing about honeycomb core is because

- 1 it's going to into space, we can't have even a drop of
- 2 water in that core. In space it would just expand and
- 3 blow up that part. So it's very critical. We only use
- 4 this on the kind of parts where we can't use water or we
- 5 can't use corrosives, because the alternatives tend to be
- 6 either acidic or basic in their action and how they work
- 7 to remove paint. And we also have really small runs, so
- 8 we don't have any kind of production line.
- 9 I just brought a couple of examples. I'll pass
- 10 these around. These are just some products we recently
- 11 made, so that one landed on Mars. And we made one, and
- 12 so it needed to work. Obviously, it will be a few years
- 13 until we can send a mechanic there. (Laughter.)
- 14 That concludes my remarks. Thank you.
- MS. RASMUSSEN: Thank you very much.
- MR. KURUCZ: Mm-hmm. Thank you.
- MS. RASMUSSEN: Any other comments from those
- 18 in the room? Okay. I'm not seeing any.
- 19 We have one that came in yesterday afternoon
- 20 after our commenting period had ended, so I will read it
- 21 today. Unfortunately, the person that they wrote it
- 22 towards is not here with us today, but I'm hoping she's
- 23 joining us via Webcast. So this question was from Megan
- 24 Schwarzman.
- 25 "Have you considered the CPDat Database at EPA?

- 1 It contains recent product ingredient and composition
- 2 data from active SDSs and other sources at Walmart, PG&E,
- 3 Drugstore.com, etcetera. Not California-specific, but it
- 4 would ID categories to focus on by chemical." This was
- 5 sent by Brian Penttila with the Washington Department of
- 6 Ecology.
- 7 I do not believe we have any more public
- 8 comments at this time. Seeing that we do not have any I
- 9 will close our public comment period. And I will turn
- 10 the meeting back over to our Co-Chairs.
- 11 PANEL CO-CHAIR FONG: Thank you very much
- 12 Kerry.
- 13 At this point we'll now hear from Xiaoying
- 14 about the Department's Alternatives Analysis review
- 15 process.
- MS. ZHOU: Thank you, Art, and good morning
- 17 everyone.
- 18 So this is outlined for my talk today. First
- 19 up, a quick recap of the SCP AA process. I will go over
- 20 the recap and numbers of the AA reports we expect to
- 21 receive and review this year. And then we'll talk about
- 22 some changes we anticipate for our upcoming review and
- 23 our ongoing efforts to address those changes, which
- 24 include the environment of the internal review process
- 25 and our capacity building activities. Then I will bring

- 1 up some questions for the panel's discussion.
- 2 So this is a simple flow chart of the SCP AA
- 3 process. These color blocks represent the three parties
- 4 involved in this process. The orange's steps represent
- 5 compliance actions conducted by manufacturers of the
- 6 priority products. It is typically a two-stage AA
- 7 process. The first stage of AA is a screening analysis,
- 8 which generates the preliminary AA reports. And the
- 9 second stage AA is an in-depth analysis, which generates
- $10\,$ the final AA reports. And the manufacturers also have
- 11 other compliance options. And then the blue color
- 12 represents the Department's review. And we also have the
- 13 green for the public engagement. There is a 45 public
- 14 comment period after the summation of the final and
- 15 abridged AA report.
- 16 So as you can see, the 180 days after the
- 17 priority product is listed in the regulations the
- 18 preliminary AA report is due. Then the Department has
- 19 typically 60 days to review them and to issue the Notice
- 20 of Determination.
- 21 So when will those AA reports come in? And
- 22 what are types of the AA reports and how many of each?
- 23 As Karl yesterday mentioned, for the paint
- 24 stripper with methylene chloride the preliminary AA
- 25 reports are due July 1st and so far we've got 10 priority

- 1 products notifications and covered 49 unique products.
- 2 And one of the manufacturers has already submitted the
- 3 product removal confirmation, so which leaves us
- 4 different scenarios for the remaining 48 products. That
- 5 would be removal/replacement notifications, preliminary
- 6 AA reports or abridged AA reports.
- 7 And there are going to be some scenarios for
- 8 how manufacturers choose to combine them. They could
- 9 combine them based on the brand or composition or product
- 10 tab or specific application. Or some may be conducted by
- 11 consortium, but at maximum we will get 48 different AA
- 12 reports for this product.
- 13 And for the SPF systems with the MDI, the
- 14 preliminary AA reports are due August 26. And this
- 15 Friday is going to be the due date for PPNs. And as of
- 16 the yesterday we have the 3 priority products
- 17 notifications already been submitted, which cover the 33
- 18 unique products. And we expect there is going to be a
- 19 change by this week, end of this week.
- 20 So what will the Department review those
- 21 reports for? The regs list of the general requirements
- 22 and specific contents requirements for different types of
- 23 the AA reports, and also the Department of Review
- 24 Criteria. But they are pretty general, but the reliable
- 25 information is specifically defined in the regs. And

- 1 those have been provided at the supporting documents in
- 2 your meeting. (Off mic colloquy re: slides.)
- 3 And for the preliminary AA reports once we've
- 4 received them then the AA review process starts. And we
- 5 have the 60 days to review them and issue the Notice of
- 6 Determination. That could be the Notice of Compliance,
- 7 Notice of Deficiency, Notice of Disapproval or it's a
- 8 Notice of Ongoing Review. If a Notice of Deficiency is
- 9 issued the responsible entities have 60 days to address
- 10 those deficiencies and resubmit their revised AA report.
- 11 And then the Department has 30 days to review to review
- 12 that revised AA report and issue the final determination.
- 13 And this is -- it looks a lot more complex,
- 14 because for the abridged AA report the review scheme is
- 15 quite similar as a final AA report. If one functional,
- 16 acceptable and technically feasible alternative is not
- 17 available manufacturers may submit abridged AA reports,
- 18 which skips some steps of the two-stage AA process and
- 19 speed up their R&D activities. And so the abridged AA
- 20 report has the same due date as the preliminary AA
- 21 reports, but the review scheme is the same as final AA
- 22 reports.
- 23 And after the abridged AA report is received,
- 24 so first of the 45-day public comment period starts.
- 25 Then the Department has 30 days to review those comments

- 1 and assigns a due date to the RE to address those
- 2 comments. And after the RE submits the AA report
- 3 addendum then the typically 60-day review cycle starts
- 4 again.
- 5 And there's also another pathway in lieu of the
- 6 AA process that is a Removal/Replacement Notification.
- 7 And there is some flexibilities built into this process,
- 8 given the different situations of the manufacturers. But
- 9 I'm not going to cover the more details, because of focus
- 10 of today's review is the AA reports.
- 11 Next, I'm going to talk about the challenges
- 12 for our review. There's the three main challenges or the
- 13 constraints: time, resources and decision making.
- So, the number one challenge is time. We have
- 15 a short turnaround time for the reviews, typically it's
- 16 60 days. And as I just mentioned there are some
- 17 uncertainties involved with when those AAs comes in and
- 18 how many of them. And so our effort is to address those
- 19 challenges and try to be helping folks to make our
- 20 internal review process as smooth as possible. And we
- 21 have developed an internal AA review process document,
- 22 which details the internal procedural elements and the
- 23 work priorities, so everyone on the team will understand
- 24 their roles and responsibilities. And instead of the
- 25 traditionally linear project or management approach,

- 1 agile process will be applied to expedite the process.
- 2 And because this is -- for those who are not familiar
- 3 with the agile process it is a particular project
- 4 management tool method open-use dating the field of the
- 5 software development. And because this is, for those who
- 6 are not familiar with the agile process, it is a
- 7 particular project management (indiscernible) often used
- 8 in the field of software development. And because this
- 9 is the first time for all of us to review the actual AA
- 10 reports this agile process can help to break down that
- 11 60-day review cycle into smaller sprints and daily
- 12 briefing meetings. So the staff can have an almost real-
- 13 time communication with management about some
- 14 unpredictable situations and potential issues and help to
- 15 make a quicker decision to resolve those issues.
- 16 And we also have other tracking tools to help
- 17 us to track those that work, progress and to manage our
- 18 workload more efficiently to meet that short timeframe.
- 19 In addition, we also continuously work on the
- 20 testing of the CalSAFER backend, because that's going to
- 21 be the platform for us to assign the tasks to staff and
- 22 transfer the documents and communicate our decisions with
- 23 responsible entities.
- 24 And finally we also worked with our CalSAFER
- 25 team and IT folks and the operation (indiscernible) unit

- 1 and legal. And to make sure that the environment and the
- 2 process is safe to handle the trade secret information
- 3 during the AA review process.
- 4 So the next challenge I'm going to talk about
- 5 is the resources. Due to the very unique and
- 6 comprehensive scope of the SCP AA framework it requires
- 7 unconventional skillsets of the staff to review the AA
- 8 reports. And again, this is our first time. And we
- 9 certainly have a small and new team. And while we have
- 10 to fill some expertise gap, the first thing we will do is
- 11 to leverage our existing resources and expertise within
- 12 the program and within the Department, so our efforts to
- 13 date and including the new hirings and the recruitment
- 14 and internal and external technical training and
- 15 coordination.
- And we're also conducting our own technical
- 17 research and reviewed the literature libraries for
- 18 specific chemical product combinations to educate
- 19 ourselves about those technical issues we might be seeing
- 20 in the coming AA reports.
- 21 And we also did some mockup AA reports review
- 22 to get more experience.
- 23 And the next one is about decision making. So
- 24 as we know the AA itself is not a decision-making tool.
- 25 It cannot point to a value-based decision for us. So

- 1 it's a process to collect and analyze the information to
- 2 support and inform the decision. So our review is not
- 3 just only about technical validation. There is going to
- 4 be a lot of the value-based decision making involved in
- 5 that process. And there are going to be those case-by-
- 6 case determinations.
- 7 And also, we expect different scenarios and
- 8 qualities will be seen for those upcoming AA reports. So
- 9 our efforts are including continuously proactive
- 10 stakeholder outreach and engagement activities, so we try
- 11 to provide clarification and assistance for the
- 12 compliance and to build up that trust. And our team has
- 13 also devised a completeness and technical review
- 14 checklist to document our decision rationales for
- 15 consistency and transparency.
- And we also have a sub-team who is working on
- 17 researching those different impacts of the potential
- 18 regulatory responses, given different scenarios. And to
- 19 set up a link between the AA with us and the regulatory
- 20 response. So this whole access, this whole process is
- 21 now just a paper exercise. That is really action-
- 22 oriented.
- 23 So those are the specific questions that are
- 24 also included in your meeting materials for the panel's
- 25 discussion, so we really are looking forward to hear the

- 1 tips and experience from Meg and the input from all of
- 2 you. Thank you.
- 3 PANEL CO-CHAIR FONG: Thank you very much.
- 4 So at this point I'm going to ask the panel
- 5 members if they have clarifying questions for Xiaoying.
- 6 And again, we have -- we're setting aside over an hour
- 7 and a half or more deep-dive discussions, so if you can
- 8 limit your questions at this point to just clarifying
- 9 questions. I see Mike has his sign up. Mike, Elaine,
- 10 Mike?
- 11 PANEL MEMBER CARINGELLO: Okay. Thank you for
- 12 the presentation. Well done. When you talk about the
- 13 response times, when you have the timelines, are the
- 14 response times that you lay out are those by regulation
- 15 or are those by what DTSC is estimating the timing to be?
- MS. ZHOU: That's by regulation
- 17 PANEL MEMBER CARINGELLO: Okay. That's what I
- 18 was thinking. And are the number of revisions that an RE
- 19 can make is that also limited by regulation?
- MS. ZHOU: Yes.
- 21 PANEL MEMBER CARINGELLO: Okay. And it just
- 22 seems to me that between the response times and the
- 23 number of revisions it's going to be difficult -- and it
- 24 goes to your first question -- it's going to be difficult
- 25 to balance how you have a robust discussion. And really

- 1 meet up with RE and say, "Okay. Here's what we're really
- 2 looking for." And give them time to give you a good
- 3 response, versus having a fast program, so you can get
- 4 more throughput.
- 5 MS. ZHOU: Yeah, that's true.
- 6 PANEL MEMBER CARINGELLO: Thank you.
- 7 MS. ZHOU: Thank you.
- 8 PANEL CO-CHAIR FONG: Thanks Mike.
- 9 Elaine?
- 10 PANEL MEMBER COHEN-HUBAL: So this is a very
- 11 quick one, there was the slide with the blue box of
- 12 comments? I just didn't get to read it.
- MS. ZHOU: The first one?
- 14 PANEL MEMBER COHEN-HUBAL: The box in the --
- 15 can I just --
- 16 ACTING DEP. DIRECTOR PALMER: Reliable
- 17 information?
- 18 ACTING DIRECTOR WILLIAMS: Yeah.
- 19 PANEL MEMBER COHEN-HUBAL: What was it?
- 20 ACTING DEP. DIRECTOR PALMER: The reliable
- 21 information box?
- 22 PANEL MEMBER COHEN-HUBAL: Yeah. Do you mind
- 23 just putting that up while people are asking their
- 24 questions? I just didn't read it. Thank you.
- MS. ZHOU: Yes. Sorry, this is the one that's

- 1 kind of screwed.
- 2 PANEL MEMBER COHEN-HUBAL: Okay. Can you just
- 3 leave it for a minute?
- 4 ACTING DIRECTOR WILLIAMS: And again, that's
- 5 straight out of the regulations.
- 6 MS. ZHOU: Yeah.
- 7 PANEL MEMBER COHEN-HUBAL: Okay. So do we have
- 8 that? We don't have that part in here?
- 9 MS. ZHOU: You probably don't have that. It's
- 10 in the definition section for the reliable information.
- 11 PANEL MEMBER COHEN-HUBAL: Thank you.
- 12 PANEL CO-CHAIR FONG: Okay. I have Kelly next.
- 13 PANEL CO-CHAIR MORAN: Yeah, thank you,
- 14 Xiaoying. This is really helpful. And although our job
- 15 is really to talk to you about science, I appreciate that
- 16 you shared with us some of the management approaches that
- 17 you're using so we can see how the team work and
- 18 preparation fits in with our discussion today. And where
- 19 you're headed, which is super-exciting. It feels like
- 20 you're just doing so much groundwork to be ready for
- 21 this.
- I wanted to make sure I understood the
- 23 timeframes of when the AAs would arrive. And just to
- 24 make sure I correctly grasped the workload and what we're
- 25 advising on in this first round. So the AAs are due, the

- 1 first set are due on July 1, but they could come before
- 2 July 1, right?
- 3 MS. ZHOU: Yes. They can come any time before
- 4 July 1, so some may come very close to the due date, but
- 5 some may come earlier.
- 6 PANEL CO-CHAIR MORAN: Yeah. Most people seem
- 7 to want to do things on the due date, but some people are
- 8 like me and come a week or two early, because we're
- 9 nervous about doing it wrong. I'm the one who files
- 10 taxes early. You know, how I am. So, but you still
- 11 only --you don't have 60 days from July 1 you have 60
- 12 days from when they file?
- MS. ZHOU: Yes.
- 14 PANEL CO-CHAIR MORAN: Okay.
- MS. ZHOU: When they file.
- 16 PANEL CO-CHAIR MORAN: So there will be --
- MS. ZHOU: When we receive that.
- 18 PANEL CO-CHAIR MORAN: Okay. So there will be
- 19 some ruling in the review and that you'll have to respond
- 20 to some of them before you've completed the reviews on
- 21 others.
- MS. ZHOU: Mm-hmm.
- 23 PANEL CO-CHAIR MORAN: And the 60 days includes
- 24 the time for preparing your written response and internal
- 25 review of that?

- 1 MS. ZHOU: Yes. All of them.
- 2 PANEL CO-CHAIR MORAN: Yes. That is, for those
- 3 who don't work in government that's a very big deal, so
- 4 that's having dealt with 60-day review periods myself.
- 5 And then the review criteria, I think they were
- 6 underneath the thing that Elaine was just looking at,
- 7 they're pretty broad right?
- 8 MS. ZHOU: Yeah.
- 9 PANEL CO-CHAIR MORAN: Yeah. So and that's all
- 10 the reg says about it, right?
- 11 MS. ZHOU: Yeah, review criteria down.
- 12 PANEL CO-CHAIR MORAN: So you're really looking
- 13 for completeness and accuracy?
- MS. ZHOU: Yeah.
- 15 PANEL CO-CHAIR MORAN: So scientific quality.
- MS. ZHOU: Yeah.
- 17 PANEL CO-CHAIR MORAN: So that's typical.
- 18 MS. ZHOU: For the reliable information it's
- 19 about the quality.
- 20 PANEL CO-CHAIR MORAN: Yeah. So the criteria
- 21 here are pretty typical to the types of things that we
- 22 assigned as we'll be doing our peer reviewing something,
- 23 we'd be really thinking through that. But perhaps a
- 24 little more depth on the quality of the data underlying
- 25 the assessments, so oftentimes when we we're peer

- 1 reviewing an article we don't have access to that part.
- MS. ZHOU: Mm-hmm.
- 3 PANEL CO-CHAIR MORAN: Okay. That helps a
- 4 bunch. Thank you.
- 5 MS. ZHOU: Thank you.
- 6 ACTING DEP. DIRECTOR PALMER: Can I just add a
- 7 quick point of clarification?
- 8 PANEL CO-CHAIR MORAN: Yes.
- 9 ACTING DEP. DIRECTOR PALMER: Is that our
- 10 regulations do allow responsible entities to collaborate
- 11 and coordinate on their AAs. And so for both of these
- 12 priority products there are trade associations that have
- 13 indicated they are going to be doing some of that. We're
- 14 not sure to what degree, so the numbers that Xiaoying
- 15 presented are that are sort of worst-case scenario in
- 16 terms of numbers. But we might get elements of an AA
- 17 that are collectively done or we might get an AA, one AA
- 18 that represents five responsible entities. Again, we
- 19 don't know yet to what degree they'll take advantage of
- 20 that.
- 21 And it's potentially complicated, because
- 22 they're competitors and they are trying to figure that
- 23 out. But we are coordinating with them directly, so
- 24 we'll get a little more insight to that as time goes on.
- 25 PANEL CO-CHAIR MORAN: So do you think you're

- 1 going to get one AA per manufacturer or one AA per
- 2 product or -- because I saw on methylene chloride, I
- 3 think it was 10 manufacturers and 48 products? So what
- 4 would your expectation be for the maximum, 10 or 48 some
- 5 number in between?
- 6 ACTING DEP. DIRECTOR PALMER: Well, the
- 7 theoretical maximum is that we could get one per product.
- $8\,$ But I think realistically, because a lot of them are
- 9 similar there's going to be sort of a nesting of the
- 10 materials that may be packed. So there's going to be a
- 11 lot of overlap, I suspect, with any termed responsible
- 12 entity and perhaps across responsibility. We're not
- 13 really sure.
- 14 ACTING DIRECTOR WILLIAMS: And I would just say
- 15 that I think the specificity of the product definition in
- 16 terms of the application is going to determine whether or
- 17 not there's a difference in the products. In other
- 18 words, we've had so many conversations about what's the
- 19 intended use of the product. And if that's what's used
- 20 to define the product then I would expect it to have an
- 21 unique AA based on that functional requirement.
- 22 ACTING DEP. DIRECTOR PALMER: So more than 10
- 23 if you're in the 48.
- 24 PANEL CO-CHAIR MORAN: Okay. Thanks.
- 25 PANEL CO-CHAIR FONG: Thank you, Kelly.

- 1 Jack?
- 2 PANEL MEMBER LENARD: You referred to the
- 3 internal AA review process document. I don't have --
- 4 have we seen a copy of that? Because that would be of
- 5 interest for, at least, for me to review and see what
- 6 things you may want to add or what things you may have
- 7 forgotten about or didn't realize that people do in
- 8 conducting AAs.
- 9 MS. ZHOU: I don't know, Tony?.
- MR. LUAN: Oh yeah, we do have an internal
- 11 document. But it's mostly to assign roles and
- 12 responsibilities. It's not something that we've prepared
- 13 for external consumption, but we could clean it up and
- 14 send it out. But I don't think it would very be useful.
- 15 PANEL MEMBER LENARD: Oh, just because you
- 16 referred to it I just wasn't sure what that was. Was it
- 17 just strictly the process or did it go into more detail
- 18 as to who does what and what types of things do you look
- 19 at?
- 20 MR. LUAN: Not what types of things you look
- 21 at, but who does what.
- 22 PANEL MEMBER LENARD: Okay.
- 23 MR. LUAN: So it assigns main responsibilities,
- 24 the timeframes and other people.
- 25 PANEL MEMBER LENARD: Okay.

- 1 PANEL CO-CHAIR FONG: Are there any more
- 2 clarifying questions? If not, Xiaoying, thank you very
- 3 much.
- 4 MS. ZHOU: Thank you.
- 5 PANEL CO-CHAIR FONG: Now we're going to switch
- 6 gears and hear from Dr. Whittaker of ToxServices on her
- 7 extensive experience reviewing AAs and her
- 8 recommendations for AA reviews. Meg?
- 9 DR. WHITTAKER: Great. Thank you.
- 10 Well, reviewing AAs has made me very humble.
- 11 And you'll learn to be humble too throughout the process.
- 12 Then you do have quite a challenge, so I've been very
- 13 lucky in that I haven't had to look at dozens of AAs at
- 14 once with people from many, many disciplines. The types
- 15 of AAs I've looked at have really -- I do have a degree
- 16 in economics, which is kind of funny that not many people
- 17 know about, but it's been very economic-light. And the
- 18 focus has always been on hazard and performance, but
- 19 you've got the full Monty. So I'm going to just give you
- 20 some recommendations. What I tell you today are just my
- 21 recommendations from the school of hard knocks. And it's
- 22 been very hard knocking.
- 23 And whenever I try and train someone in how to
- 24 either be a risk assessor or an alternatives assessor or
- 25 a chemical hazards assessor, I would say, "First of all

- 1 you've got to know what your goals are and what questions
- 2 are you trying to answer." And obviously you know your
- 3 guide, because you wrote it. And it's a very good guide.
- 4 I think the manufacturers out there who take the time to
- 5 read it and dig into Chapter 11 will hopefully give you a
- $6\,$ good work product for you to work with and make your
- 7 decisions on.
- 8 And you do have a lot of challenges, because as
- 9 you go into different priority products and identify
- 10 different chemicals, the tools and techniques and methods
- 11 that companies are going to use to identify safer
- 12 alternatives, if they do that as opposed to one of the
- 13 other alternate approaches, they're going to have a
- 14 different game plan. So you're not going to write a
- 15 beautiful SOP that will identify every single step to
- 16 follow every single time. So don't get frustrated. I
- 17 learned a long time ago not to be frustrated.
- 18 And the goal, remember what the responsible
- 19 parties are supposed to be doing for you is to give you
- 20 reliable, valid and plausible Alternatives Assessment, so
- 21 that by the time someone knocks on your door they should
- 22 have already thought of all those things. And you may
- 23 want to consider more and more workshops and over-
- 24 communicate that, they should give you something that's
- 25 ready to go. They should understand that those are the

- 1 goals. And you've given them a great checklist. So I
- 2 wish this would have existed a few years ago, because it
- 3 would have made my life a lot easier and I would have had
- 4 less gray hair.
- 5 My first tip is that you have to understand the
- 6 product type. Also, to save face with a client I've
- 7 learned, when I started looking at boat paints, I knew a
- 8 little bit about paints from working on Cradle to Cradle
- 9 assignments. But I learned right away that if you don't
- 10 even know the vernacular of what they're speaking they're
- 11 not going to open up and tell you the story of their
- 12 product and first of all, why they were using a Chemical
- 13 of Concern.
- We heard this morning from Lockheed Martin why
- 15 methylene chloride is being used. And most people that I
- 16 know are not intentionally using a hazardous and risky
- 17 chemical without reason. So understand, read everything
- 18 you can. Order the Kirk-Othmer. Even though it's
- 19 getting older it's still a wonderful place to start to
- 20 understand the basics of the product type and data mine
- 21 that. Data mine Google Books -- sorry, Art had to say
- 22 Google. But get to know it. You need to understand it.
- 23 Even if you're a toxicologist or an economist you need to
- 24 know the background of that product type. It will make
- 25 it so much easier. Learn from me.

- 1 And I always say to my staff, "You've got to
- 2 understand the 5Ws and 1H as to why is that Chemical of
- 3 Concern being used in the product? How is it used? Why
- 4 is it used? Where is it used? Where is it used in the
- 5 process? Is it a contaminant? That will make it so much
- 6 easier. And I look at that and I think, "I wish someone
- 7 would have told me that." So if you know that it will be
- 8 a lot easier.
- 9 And it will be more fun too. I think for
- 10 those, we're all inquisitive or we probably wouldn't be
- 11 here, I look at it like a challenge to try and
- 12 understand. And also to figure out whether the proposed
- 13 alternatives really make sense. Because some people
- 14 propose alternatives I see, and there's no way that the
- 15 alternative would fly. And so that will help you, too,
- 16 to see which proposed alternatives just won't work.
- 17 Don't try and assess something you're not
- 18 trained to do or if you're doing that work with someone
- 19 more senior. Junk in equals junk out. And you're going
- 20 to get better as time goes by. When I look at my first
- 21 GreenScreen, it scares me, from 2008. And you know, we
- 22 keep it as a joke to remember -- or my first risk
- 23 assessment too -- you're going to get better over time,
- 24 so I don't think anyone is expecting you to hit a home
- 25 run right away. I think in a year or two you guys are

- 1 going to be the best in the business.
- 2 But don't set yourself up for failure. You
- 3 need to understand, for those of you that are assigned to
- 4 certain parts, if you don't even understand the
- 5 difference between reproductive and developmental
- 6 toxicology, learn now. Buy that Casarett and Doull's and
- 7 dive into it. And ask questions, don't be shy. Don't be
- 8 embarrassed. Get on those workgroup calls and say, "I
- 9 have no idea."
- I work with a really good toxicologist named
- 11 Nancy Linde who came on board a few months ago. And what
- 12 I love about her is that she's so humble. She'll say, "I
- 13 have no idea." And you know what? She probably does
- 14 know, but it makes it so much easier. So you need to
- 15 know every aspect. If you don't anything about exposure
- 16 assessment pull every single article you can pull, make
- 17 it open access. I do it on the cheap, I go to PubMed and
- 18 I read everything out there that my competitors have
- 19 done, so that I can understand something new. And I
- 20 email them, I pick up the phone and call them. If
- 21 they're going to write about, they should know what
- 22 they're talking about.
- 23 And remember, you need to identify reliable, as
- 24 we've already heard that term -- Klimisch is our friend -
- 25 and appropriate test methods, hazard frameworks and

- 1 exposure models.
- 2 And remember, the people who are submitting to
- 3 you are supposed to be experts in their product type.
- 4 But they're not necessarily an expert at LCA, there are
- 5 very few people who are experts at LCA that I've ever
- 6 met, or Economics, or Chemical Hazard Assessment. Get
- 7 full copies of those test reports. If they're doing
- 8 emissions testing and it's only on one day and it's a
- 9 volatile chemical, well not on volatile chemicals; that's
- 10 probably not a good test. Those generally will go up and
- 11 up and up and maybe they'll go down. But how do you know
- 12 you're looking at the right emissions testing? Get that
- 13 full report, see what those laboratories are testing.
- Most laboratories we work with are very
- 15 friendly. And I can imagine that they would give you a
- 16 free Webinar or educate you in their methods. The ones
- 17 we work with are very proud scientists and yeah, because
- 18 they have their proprietary test methods, so they're
- 19 probably not going to want to give you their protocols.
- 20 But they'll be happy to talk to you about, "Well, what's
- 21 the basics of emissions testing." And "What's a Tedlar
- 22 bag? You know that's not really an emissions test? It
- 23 does collect volatiles, but that's different than an
- 24 emissions chamber.
- 25 So ask lots of questions and take great notes.

- 1 My laboratory notebook, my super-secret, top-secret one -
- 2 I had to say it a couple of times -- is stuck in my
- 3 office. And I keep a Xerox duplicate in case there's a
- 4 fire or an earthquake or something. But you're going to
- 5 need to take a lot of notes and then share with each
- 6 other.
- 7 Cited publications are interesting, because you
- 8 really need to see what they're talking about. So I'm
- 9 not too sure on what the power you have to say, "Well, we
- 10 want to see full copies of every cited publication," but
- 11 that's kind of important for you to really dig into it.
- 12 So if you have the authority to do that it might be a
- 13 good thing. So you're going to get buried in paperwork
- 14 relatively quickly, but at least you'll be able to dig in
- 15 and see what's the basis. I have just oodles of
- 16 publications in my office.
- 17 And then it's important for you to take a look
- 18 at who's performing these AAs that you are going to be
- 19 reviewing. Are these people qualified to perform an AA?
- 20 If they've never, if they're not a risk assessor or a
- 21 chemicals hazards assessor or they've never worked in a
- 22 laboratory are they really qualified to do it? It
- 23 doesn't necessarily mean that that AA is going to be sunk
- 24 from the get-go, but take a look at who they are. That's
- 25 really important, because you're going to see a whole

- 1 gamut of quality, I'm guessing.
- 2 It's important for the hazard frameworks, and
- 3 test protocols, and test methods that are used to
- 4 classify hazards be really reliable and they be robust.
- 5 All of you who are toxicologists are familiar with OECD
- 6 Test Guidelines. The Klimisch scores that are used to
- 7 rate reliability are based on, are from BASF, but were
- $8\,$ done to assess OECD Test Guideline studies. They are
- 9 there for the reading. And they're not light reading,
- 10 but you need to get to know them. You need to download
- 11 the Klimisch article from RTP and get to know that as
- 12 well.
- I would recommend, if you're looking at
- 14 exposure modeling, those AAs ideally should completely
- 15 document all exposure equations and calculations. I'm
- 16 always very suspicious when I see, for example, a Safe
- 17 Harbor Report, and they've come up with let's say an NRSL
- 18 and there's no basis for it. Or they quantify the
- 19 exposure to a Prop 65-listed chemical, for example, and
- 20 they won't disclose the equation that was used to
- 21 calculate the exposure. Whether it's inhalation or
- 22 indirect oral, you should be able to see everything.
- 23 That should be part of the process. And in Chapter 11 of
- 24 your Guidance you've made it very clear you want to see
- 25 it all. So that's quite key.

- 1 The test methods and the frameworks, as I've
- 2 said, that are used should be reliable. And it's really
- 3 important that those undergo external validation. We
- 4 want to make sure that they're reliable. We want to make
- 5 sure that they're scientifically based. And that they're
- 6 appropriate to answer the question at hand. And there's
- 7 a really nice OECD Guideline -- the hyperlink works
- 8 though -- 34, that talks all about this. Because what's
- 9 going to happen is it's not just GreenScreen anymore,
- 10 there are lots of other chemical hazard assessment and
- 11 tools, SciveraLENS.
- 12 Well, you need to ask yourself has that
- 13 undergone external evaluation. Has someone smarter than
- 14 all of us in this room looked at that and said, "This is
- 15 a great way to assess hazards. If not just make sure you
- 16 double-check and look under the hood. Or else you may
- 17 find that, you know, something saying, "Sure. This is a
- 18 safer alternative," has completely overlooked an
- 19 important hazard endpoint. So I just warn you on that,
- 20 because I've seen that really mess up some clients.
- You're going to have to have this dynamic,
- 22 ongoing training. It's like a marathon, you're never
- 23 going to stop running. I'm constantly, maybe relearning
- 24 over and over and over how to be a better alternatives
- 25 assessor. I highly recommend that I try and do it on the

- 1 cheap, I'm a cheap marathon runner, that you're going to
- 2 have to juggle your work and you've got a timeline. But
- 3 I'd recommend that you get involved.
- 4 I really have enjoyed the recent discussions of
- 5 the BizNGO Hazard Group. We've been talking about
- 6 endocrine disruption, which is front and center right now
- 7 all over the world. And they get presenters from all
- 8 over world giving their two cents. And we share
- 9 publications and discussions, so you just have email
- 10 Shari Franjevic to participate. And there's no cost.
- 11 And I'd highly recommend you become
- 12 GreenScreeners. Even if you're not a toxicologist we
- 13 contribute our staff for free as instructors, because
- 14 that was done to us. We were trained by someone more
- 15 senior. And the registration deadline for the different
- 16 courses are coming up, so consider joining us. It's not
- 17 scary and we're friendly. I'm friends with people all
- 18 over the world now because of it.
- 19 You heard about the NAM workshop that you can
- 20 also participate in remotely that I mentioned yesterday.
- 21 And then of course our community and as an alternatives
- 22 assessor you're only as strong as A4, so we're always
- 23 looking for members. And we know that we need to keep it
- 24 interesting and grow the profession. And believe me,
- 25 you're going to want to have someone to fill your shoes

- 1 in a few years when you guys are awesome alternatives
- 2 assessors. And just think, if we have A4 growing someone
- 3 will coming knocking on your door and you won't have to
- 4 go through this entire learning process. It'll be a
- 5 little bit easier, so I encourage you to join A4, it's
- 6 really inexpensive.
- 7 So these are some of my tips. It's always
- 8 going to different; it's never going to be the same thing
- 9 with any AA. And I'm always happy to share my little
- 10 bits of knowledge with anybody if you'd like to contact
- 11 me. But those are some of my tricks and tips. Thank
- 12 you.
- 13 PANEL CO-CHAIR FONG: Meg, thank you very much
- 14 for a very informative presentation, and those excellent
- 15 recommendations. And I especially appreciate you taking
- 16 time out of your very busy schedule and flying out from
- 17 D.C. to join us for the last two days.
- 18 At this point let me see if panel members have
- 19 any clarifying questions.
- DR. WHITTAKER: Oh, and I just had one more
- 21 slide I wanted to show. So this is kind of interesting
- 22 and it relates to reliability. About 40 percent of the
- 23 toxicity studies in the America in the '70s were
- 24 performed by Industrial Bio-Test Laboratories. And I
- 25 know that the older toxicologists here who I'm speaking

- 1 to know the whole story of IBT. But the fraud and animal
- 2 abuse and plagiarism at IBT created the whole Good
- 3 Laboratory Practices movement. And still, because there
- 4 were thousands of studies you are going to find IBT
- 5 studies cited in AAs to substantiate safer chemical
- 6 selection.
- 7 And it's interesting. I just saw another one
- $8\,$ pop up in a risk assessment that was trying -- they were
- 9 using their chronic study as the basis. And not all IBT
- 10 studies are suspect. The non-acute ones are the ones
- 11 that are considered unreliable, so it would Klimisch 3,
- 12 right? And so just keep an eye for that, because this
- 13 will pop up -- it was amazing -- over and over.
- 14 And I find it -- it's kind of a fun story to --
- 15 I mean, it's sad, but it's a fun story to tell to
- 16 scientists as to, "Well, how did Good Laboratory
- 17 Practices come about?" And if you google IBT you'll read
- 18 about the whole story.
- 19 But this is wording that we use. And the
- 20 important part about this is that it cites to a great
- 21 OECD guidance document from 2005, which was quite some
- 22 time ago, but it's still a great document. It's the
- 23 "Manual for the Investigation of HPV Chemicals: Data
- 24 Evaluation." Take a whole afternoon and probably a whole
- 25 box of cookies and dig into that. But it will talk to

- 1 you and lead you through, really, how to look at data and
- $2\,$ how to look at suspect data. Because not all IBT data is
- 3 unreliable or are unreliable, but a good part are.
- 4 So I thought about this last night, because I
- 5 was corresponding with a client overseas who had this
- 6 issue with the study. But just remember that. I think
- 7 this is another really good trick to teach you or tip.
- $8\,$ And download that reference. And the OECD website has
- 9 other good citations too, so thanks.
- 10 PANEL CO-CHAIR FONG: Thank you.
- MS. ZHOU: Will all the slides be posted?
- 12 UNIDENTIFIED SPEAKER: Yes.
- MS. ZHOU: Okay, thank you.
- 14 PANEL CO-CHAIR FONG: Let me just go around,
- 15 unless I received their clarifying questions for Meg.
- 16 Ms. Williams?
- 17 ACTING DIRECTOR WILLIAMS: I'm cheating, I
- 18 don't know that this is a clarifying question or
- 19 something for discussion, but I was interested in kind of
- 20 your workflow process, how iterative your review process
- 21 is. Do you do a first overall scan of what you have and
- 22 just give it a kind of high-medium-low quality? And I
- 23 don't know -- that's not entirely a clarifying question,
- 24 but I do want to get it out there quickly.
- 25 PANEL CO-CHAIR FONG: No, that's okay.

- DR. WHITTAKER: We reverse engineer it. So we
- 2 have our own checklist, kind of like you do in Chapter
- 3 11. And especially if you're going to be looking at 20
- 4 at the same time, another issue you're going to have is
- 5 trying to keep, make sure you treat each of those
- 6 equally. So I reverse engineer it and I'll look at how
- 7 well -- I'd print out your checklist. If I were you, if
- $8\,$ I'm working for Meredith, I would get my checklist. Or I
- 9 would make it into a checklist, because you're probably
- 10 going to want -- you may want to, I don't know, we have
- 11 QC at most processes where decisions are made. And
- 12 triage it and see which ones go to the top of the pile
- 13 and which ones go to the bottom of the pile. And the
- 14 tougher ones will go to the more senior staff, it's sad
- 15 to say, because those will need more CPR.
- 16 And so we reverse engineer it. And figure out
- 17 right away do they even need the sniff test for
- 18 evaluation, because some don't. Hopefully none of yours
- 19 will.
- 20 PANEL CO-CHAIR FONG: Thank you. Ken?
- 21 PANEL MEMBER ZARKER: A question, I appreciate
- 22 your presentation. One thought I had is, because DTSC is
- 23 a public agency and this, just the normal email dialogue
- 24 that will go all along among the staff as they evaluate
- 25 these, are all subject to open records. And so do you

- 1 see any potential issues there that you maybe don't
- 2 experience in the private sector that you would think
- 3 about if you were in our shoes, in their shoes doing this
- 4 work?
- DR. WHITTAKER: Yeah, that's a good point.
- 6 Yeah, you'll have to learn to be PC. Yeah, that's a --
- 7 you have to -- you have another layer of yes. And
- 8 obviously everyone should be treated with respect. And I
- 9 don't think industry would use it against you if it's a
- 10 junior staff member and they're not familiar with the
- 11 Henry's law of constant and they don't understand
- 12 something. But yes, you'll have to make sure your staff
- 13 are aware.
- And because email, we use email as you're not
- 15 going to run to everyone's office, and we use email a lot
- 16 to communicate when we split apart different parts of an
- 17 AA. So yes, that's very true. So you're going to have
- 18 to learn PCA all the time, because it is discoverable,
- 19 you're right. Good point.
- 20 PANEL CO-CHAIR FONG: Thank you, Ken.
- 21 Are there any more clarifying --Kelly?
- 22 PANEL CO-CHAIR MORAN: Actually, I didn't stick
- 23 my card up, I broke the rule.
- Meg is your approach and workload different
- 25 when you review a risk assessment as compared to an AA

- 1 and if so, how?
- DR. WHITTAKER: Yes, because a risk assessment
- 3 will be very focused on one end point and generally one
- 4 person. If we're reviewing -- so we create our own risk
- 5 assessments, but we also peer review or help clients who
- 6 decide they want to perform their own risk assessments.
- 7 That will generally just go to one staffer who then will
- 8 look at it, write it up and it gets QCed before it goes
- 9 out.
- 10 So this is different, because you have so many
- 11 other people. You've got an entire team involved. And
- 12 it's unusual for us. We'll have maybe at the most two
- 13 people work on a risk assessment. Maybe someone will do
- 14 benchmark dose modeling if it's super-complex. And
- 15 another toxicologist will write up or evaluate the
- 16 studies.
- 17 This is a different kettle of fish, because
- 18 you're going to have to parse out different parts of the
- 19 evaluation depending on which stage of the AA. I think
- 20 the second stage will be a little easier, in my opinion.
- 21 PANEL CO-CHAIR MORAN: So when you're talking
- 22 about risk assessment, you're talking about one with a
- 23 single end point, so not the kind where you're assessing
- 24 the risk against other chemical against all the end
- 25 points. So (indiscernible)

- 1 DR. WHITTAKER: Right. Yeah.
- 2 PANEL CO-CHAIR MORAN: Okay, so that's a whole
- 3 different thing then.
- 4 DR. WHITTAKER: Most people out there are
- 5 performing regulatory risk assessments just to address
- 6 one health effect end point and assess whether it's an
- 7 NRSL or an MADL as opposed to "We're going to assess
- $8\,$ risks against an entire slew of hazard end points and
- 9 figure out the likelihood of harm."
- 10 PANEL CO-CHAIR MORAN: Yeah, that's the kind I
- 11 review all the time. So that's why I'm asking that
- 12 clarifying question, because it's completely different
- 13 than what you described.
- DR. WHITTAKER: Yeah, so what would you do? So
- 15 you -- well I'll just --
- 16 PANEL CO-CHAIR MORAN: I'll address that when
- 17 we get to the staff review. Because I actually have a
- 18 lot of experience doing 60-day reviews for government
- 19 agencies, so let's wait till discussion, okay?
- DR. WHITTAKER: Okay.
- 21 PANEL CO-CHAIR FONG: Let me ask one last
- 22 question right now. Meg, how often do you have to pull
- 23 in external experts to cover something that you might not
- 24 have, in-house expertise?
- DR. WHITTAKER: Less than 20 percent of the

- 1 time. It also gets to be very expensive. And yeah.
- 2 PANEL MEMBER BLAKE: Can I follow up on that?
- 3 DR. WHITTAKER: Mm-hmm.
- 4 PANEL MEMBER BLAKE: Where do you need that
- 5 external expertise? Where is it needed?
- 6 DR. WHITTAKER: Usually LCA. The economics
- 7 that have been done thus far on most AAs are pretty, I
- 8 don't want to say easy, but they're very -- they're more
- 9 qualitative than quantitative. And the performance
- 10 testing is easy to understand. It's the LCA part that is
- 11 challenging.
- 12 PANEL MEMBER BLAKE: Thank you.
- 13 PANEL CO-CHAIR FONG: Are there any more
- 14 clarifying questions? If not Meg, again, thank you so
- 15 much.
- DR. WHITTAKER: Oh, thank you for having me.
- 17 PANEL CO-CHAIR FONG: At this point let me turn
- 18 the mic over to my Co-Chair to start the in-depth
- 19 conversation on AA reviews.
- 20 PANEL CO-CHAIR MORAN: Can I make some comments
- 21 first?
- 22 PANEL CO-CHAIR FONG: Yes, please.
- 23 PANEL CO-CHAIR MORAN: But that's not a good
- 24 Chair role, so do you mind sharing for a couple more
- 25 minutes?

- 1 PANEL CO-CHAIR FONG: Absolutely.
- 2 PANEL CO-CHAIR MORAN: Okay. I wanted to put
- 3 out here I do a lot of review of pesticide risk
- 4 assessments. So there they're looking at one chemical
- 5 and all of its various uses and end points across the
- 6 whole array of human and environmental health. And I
- 7 have been doing this since 1999. Most of what I review
- 8 are EPA risk assessments, but I also review -- and
- 9 there's a lot of stuff published in the literature as
- 10 well. And so although I'm focused on aquatic I've also
- 11 had likely for a dozen years, anyway I've reviewed the
- 12 human health ones on a lot of them.
- 13 And a couple of parallels here: a really
- 14 important parallel, a super resource limited, I'm working
- 15 for government agencies and have access to agency staff
- 16 to help with the peer review. So it's all agency-funded,
- 17 but nowhere near as the depth of experience and the
- 18 skills that DTSC has thank goodness for that. So there
- 19 will be things that I know you're going to be able to do,
- 20 and much broader than my experience.
- 21 The pesticide risk assessment process,
- 22 particularly from EPAs, they've started batching things.
- 23 So at first they were coming out one at a time, so I had
- 24 time to really dig in and go through all this stuff and
- 25 access the experts and so forth, per just one risk

- 1 assessment. Now they're batching them at 20 or 30 at a
- 2 time and they have the same 60-day review period. So I
- 3 was -- when the regs were proposed and the science panel
- 4 advised on that, I was one of the strong advisers against
- 5 tying to the 60-day review period, because of having
- 6 extensive experience with that.
- 7 And part of the problem as I alluded to earlier
- $8\,$ is that you need to do all the science work, but still
- 9 leave enough time for that science/management
- 10 communication in making the decisions. For the
- 11 organizations that I work for there's typically a three-
- 12 to-four-week review process between the draft set of
- 13 comments and the ability to submit them, which leaves an
- 14 extremely short period of time for the science work to
- 15 occur. Especially when you're working on multiple ones
- 16 at once.
- 17 So I have great appreciation for the challenges
- 18 ahead of the staff here and the compression of that time.
- 19 So I do have a few thoughts from my experience.
- 20 The first one is kind of what Meg said, that you can do a
- 21 once-over on a risk assessment and pretty quickly see the
- 22 overall quality of it. And it's over and over and over
- 23 again. I've reviewed so many of them now it's easier
- 24 after you've reviewed a bunch. But you all have reviewed
- 25 a whole bunch of AAs, so when you were assessing them for

- 1 California work, so I think you have more experience than
- 2 you think you do. So I just want to let you have a
- 3 little more confidence that way. Great.
- As the more you review the more you can see,
- 5 right away, the quality and where that risk assessment --
- 6 or in this case, the AA, is headed.
- 7 The biggest focus of my review at this point
- $8\,$ has been on what's missing. So that's the reason that
- 9 it's so great that you all have so many PhDs on the
- 10 staff. Because one of the things the scientists learn,
- 11 as we proceed through professional training, is first
- 12 we're examining the information, looking at the
- 13 methodologies, those kinds of things; looking as facts.
- 14 As you study for your PhD the big thing that I learned in
- 15 my PhD is to find the holes. What's wrong? What's
- 16 missing? The really big picture kind of stuff. And so
- 17 I'm super-psyched that you have so many PhDs and folks
- 18 who have that level of experience on the team. Because
- 19 the biggest thing in reviewing them isn't what's there,
- 20 it's what's not there. And so that's super-huge.
- In this case I think keeping your eye on the
- 22 ball is really important, what really matters. So there
- 23 are lots of things that are wrong in the documents that I
- 24 review, but only some of them matter. And so you're not
- 25 going to be able to review every underlying document for

- 1 everything that's there. And just coming to accept that
- 2 is hard, it's really scary to say, "Oh, I'm just going to
- 3 not be able to do everything." And one thing I do is
- 4 where I can, benchmark with other sources. So you have a
- 5 tremendous opportunity to benchmark if there's enough
- 6 overlap in the review times on the AAs, to benchmark them
- 7 against each other.
- 8 And the second thing is to really focus on that
- 9 the ball here is the AA work plan. So keep your eye on
- 10 the ball. The ball in the first phase AA is getting the
- 11 right AA work plan for the second phase. So does it have
- 12 the right alternatives? So I'm always looking at the
- 13 pesticide risk assessment, at do they have the correct
- 14 description of all the uses and the pathways and so
- 15 forth? And you're going to be asking the same question,
- 16 "Are all the uses covered? And "Are all the exposure
- 17 pathways out there and covered? And which ones are
- 18 important?" That's how you're going to get to the
- 19 figuring out what the relevant factors are. You want to
- 20 make sure the right relevant factors are carried over
- 21 into the second phasing AA, so that's the ball.
- 22 So those are some ways that I use to organize
- 23 my review; do the once-over, try to figure out what's the
- 24 quality here, what are the most important things from the
- 25 perspective of the purpose of my reviews that we were

- 1 doing up for the state. So that's the AA work plan. And
- 2 what's missing? So do we have the right relevant
- 3 factors? Are we missing things? Are we missing exposure
- 4 pathways? Are we missing other kinds of stuff?
- 5 So I'll come back later, perhaps, with some
- 6 more detailed comments, because I know you all have some
- 7 questions. But I kind of want to really lay that out
- 8 there.
- 9 I suspect some of the other panelists have
- 10 probably also done some reviews. A lot of times that
- 11 might be helpful, so part of my wanting to go first was
- 12 to hope that some other folks might give us some of their
- 13 approaches and workloads. Thanks.
- 14 PANEL CO-CHAIR FONG: Kelly, thank you very
- 15 much.
- 16 Jack?
- 17 PANEL MEMBER LINARD: Put that down. I want to
- 18 reiterate some of Meg's comments. I'm not a
- 19 toxicologist, I don't review the safety, but I have done
- 20 a lot of alternatives assessments by looking at plausible
- 21 substitutions. Just a couple of things Meg said really
- 22 hit home with me.
- 23 And I don't see, I've read the methylene
- 24 chloride document. I've also, the last time we were
- 25 together, there was an NPE document. Both of those

- 1 actually don't even discuss why the chemical is being
- 2 used.
- 3 Each one has unique chemistry. NPE I'm much
- 4 more familiar with, it has some very unique chemistry and
- 5 that is why it is being used, has been used in the
- 6 industry. It's chemistry that's been known for decades,
- 7 which is why, when companies try to mimic that chemistry,
- 8 they knew exactly what they had to do in order to achieve
- 9 the right level of hydrophobicity, you name it. And they
- 10 have done it. I mean, so I just want to point out you
- 11 really need -- the first thing you need to do is say,
- 12 "Why is this chemical being used for this application?"
- In the case of methylene chloride I started my
- 14 career in paint and coatings yet the paint and coatings
- 15 are not a homogeneous field. The substrate is not
- 16 homogeneous. What may work on a latex paint on wood, may
- 17 not work at all on a thermoset on steel. So I think as
- 18 you begin to review these you've got to understand the
- 19 alternatives that are being proposed may not even work
- 20 well on the particular application. So I think you need
- 21 to look at that. Are we going to confine it to just
- 22 normal household products and most always latex paints?
- 23 Some are not. Thermoset paints on plastic, you're going
- 24 to have a very different type of alternative. That could
- 25 be totally viable, but it may be very specific to that

- 1 particular coating and that particular substrate.
- 2 Methylene chloride I imagine, and again I'm not
- 3 the expert on it, may have just a perfect blend of
- 4 polarity. The fact that it's not in a water-soluble
- 5 product means you're not going to swell wood. It won't
- 6 sit on it. And that's one of the problems with water on
- 7 wood, is it swells it. And then when you're trying to
- 8 strip the paint off the wood is now not as structurally
- 9 sound as it was if you just use methylene chloride.
- 10 So I just -- you need to do all your homework,
- 11 which is what Meg said. Do all your homework. Why is
- 12 that chemical being used? And I think you'll get ahead
- 13 of the game, so that when these come in you'll be much
- 14 better prepared to do as Kelly said, more quickly assess
- 15 the comprehensiveness of that relative to what you
- 16 thought going in.
- 17 So I think that's -- and just I'm glad Meg
- 18 mentioned Klimisch scores. Industry pays a lot of
- 19 attention to the Klimisch score, which tests the
- 20 robustness of any clinical safety study. Now I'm not the
- 21 expert, but I do know when my toxicologists see a report
- 22 out there I ask them, "What's the Klimisch score?" Older
- 23 tests generally get lower scores, because they weren't
- 24 done to the same robustness that the newer tests were
- 25 done to. So Klimisch scores of 3 eh, 5 is good. So look

- 1 at that.
- 2 So I'll leave it at that for the moment. I may
- 3 come back in other comments.
- 4 PANEL CO-CHAIR FONG: Okay, thanks Jack. Thank
- 5 you very much.
- 6 Let me see if there are other panel members
- 7 that have initial reactions or preliminary thoughts about
- $8\,$ the AA review presentations and recommendations for the
- 9 staff?
- 10 So Xiaoying?
- 11 MS. ZHOU: Maybe just one follow-up question on
- 12 Jack's comments.
- 13 And I think when we do our own technical
- 14 research we found out that actually the functional
- 15 acceptance is really kind of the hard part. Although we
- 16 have the chemist, the engineer, but really to understand
- 17 the product itself it's really difficult. Especially for
- 18 like methylene chloride, it seems like there's no
- 19 industry-testing methods. And so do we just trust the
- 20 companies that say, "Now make this work," or they just
- 21 show like ones maybe using extreme time-consuming
- 22 alternatives if one does not really meet their
- 23 requirements.
- 24 So how can we -- so what is a good supporting
- 25 information to support their claim?

- 1 PANEL MEMBER LINARD: I think the one thing for
- 2 paint and coatings there is a trade association, which
- 3 does a lot of education on different types of coatings,
- 4 the National Paint and Coatings Association. There are
- 5 educational materials.
- 6 In that, again it's not methylene chloride,
- 7 it's what you're actually trying to strip off. There's
- 8 going to be a lot of information about chemistry. And
- 9 the science of that via powder coating or latex or
- 10 standard old-fashioned linseed oil-type coating, the
- 11 alkyd-type paint, so each one has different properties.
- 12 And those are the things that you're going to have to
- 13 worry about. Because methylene chloride, I think, just
- 14 gets lumped -- it works on everything, but the
- 15 alternatives may not.
- And there may be a specific alternative for one
- 17 application, which absolutely just doesn't work for
- 18 another for various technical reasons, substrate and
- 19 coating.
- 20 PANEL CO-CHAIR FONG: Yes Mike?
- 21 PANEL MEMBER CARINGELLO: So I didn't feel this
- 22 was a clarifying question. And it can kind of go both to
- 23 Meg and to Kelly now. But I thought it was really
- 24 interesting in Meg's presentation how she said you need
- 25 to get to know the product, you need to get to know the

- 1 science, so that you understand what's being presented.
- 2 But we heard earlier that really what we're looking for
- 3 is reliable information. The DTSC is not here to
- 4 actually write the AAs. They're here to review that they
- 5 got reliable information and it met the needs.
- 6 How do you -- and as you were just saying DTSC
- 7 has a bunch of very good scientists, they've got a lot of
- $8\,$ PhDs. These people know what they're doing. How do you
- 9 step back from being the scientist, being an AA author,
- 10 and how do you step back and take only 60 days and just
- 11 hit that right piece? How do you not use the science and
- 12 all that information that you've gathered ahead of time
- 13 while you're waiting for them to write it?
- It just struck me as that it's a balance, that
- 15 maybe they could be advised on how that's done before
- 16 they start to get these AAs in.
- 17 DR. WHITTAKER: Well, I know part of the
- 18 regulations say, "Well, what's submitted has to be
- 19 plausible." So for you to understand what's plausible,
- 20 at least I would need to know the basics. And I tend to
- 21 go overboard, which I don't recommend anyone to do if you
- 22 want to have a normal life. But yeah there's a balance
- 23 like Kelly said. But you have to kind of dig in and
- 24 understand, you have to feel the pain of the manufacturer
- 25 who is having to change the way that they were doing

- 1 things. And it makes it a lot easier to understand where
- 2 they're coming from, at least for me, if I understand the
- 3 basics of the product type and the chemical.
- 4 So I try and find review articles, book
- 5 chapters, I data mine Google Books. I look at patents
- 6 and come up with a story, so I'll write down and I try
- 7 and reverse engineer. And because I'm on the billable
- 8 hour people want it faster and cheaper. So if I can do
- 9 it you guys can do it, believe me. So I just reverse
- 10 engineer it, look at patents, Google Books and then
- 11 figure out how is this being used. And then by the time
- 12 you start getting those submissions you won't most likely
- 13 be overwhelmed with, "Wow. What is this product?" and
- 14 "Why are they doing this?" Hopefully. I don't know,
- 15 does that make sense?
- 16 PANEL MEMBER CARINGELLO: Yeah.
- 17 PANEL CO-CHAIR MORAN: I kind of feel like the
- 18 staff have a real leg up on this, because they did the
- 19 product profile and they've spent a lot of time in
- 20 communication with the industry. So I'm suspecting the
- 21 kinds of things we're talking about here none of them are
- 22 news, right?
- DR. WHITTAKER: Correct.
- 24 ACTING DEP. DIRECTOR PALMER: Can I just
- 25 comment on that?

- 1 PANEL CO-CHAIR MORAN: Yeah. Yeah.
- 2 ACTING DEP. DIRECTOR PALMER: I think your
- 3 point's good is that sometimes we don't give ourselves
- 4 enough credit. But I also like to view credit -- you
- 5 know, the industries that we're regulating here have been
- 6 very engaged from the get-go and have provided us a lot
- 7 of insights into their world and process. Some of them
- 8 are here today who have come out.
- 9 For example, one of the manufacturers of
- 10 methylene chloride products came out and showed how they
- 11 do their AA, the difference in performance and different
- 12 substrates and things like that. It was very
- 13 informative. The SPF community has given us a lot of
- 14 information and been engaged. So we have a fair amount
- 15 of understanding, but the devil is in the details. And I
- 16 think because the process is new that one of our concerns
- 17 about the engagement on the documents and that process as
- 18 opposed to the general knowledge, which has been pretty
- 19 good. So this is all very helpful.
- 20 PANEL CO-CHAIR MORAN: Yeah. I just feel like
- 21 in responding to Mike's question one of the key things is
- 22 for the AA, one of the key things is going to be the
- 23 selection of alternatives and the description thereof.
- 24 For my experience in viewing AAs, which is far more
- 25 limited than Meg's, the gap has been the range of

- 1 alternatives being adequate. And I think that was one of
- 2 the really huge -- yeah, one of the fundamental gaps.
- 3 But in the step that should come in the first phase has
- 4 been that range of alternatives, because California's
- 5 requirement for examination is so broad.
- 6 You know, pretty much every AA is going to need
- 7 have some sort of mechanical needs. To examine the
- 8 mechanical removal, an alternative in it, that's
- 9 completely unique in California as compared to other
- 10 places. So I'm expecting or at least for the methylene
- 11 chloride ones, so I'm expecting that questions about that
- 12 scope of alternatives are going to be really broad.
- When I'm doing my initial review, I'm looking
- 14 for those kinds of key areas that indicate thoughtfulness
- 15 and sophistication. And really, truly examining
- 16 alternatives and not -- so in a pesticide risk assessment
- 17 I'm really looking at thoughtfulness and how the uses are
- 18 described in the data transport. Here it's probably
- 19 going to be a different set of things. I think one of
- 20 those is very likely to be the description of
- 21 alternatives, the identification and description of
- 22 alternatives. How detailed and thoughtful that is. Some
- 23 of the stuff we've been talking about here likely to play
- 24 in. I don't know for sure.
- 25 And the other one is the really how thoughtful

- 1 the end points selection is. So there again I see a lot
- 2 of missing stuff. One thing I forgot to mention earlier
- 3 is that a key thing for me is having the document I'm
- 4 reading not reflecting the knowledge of the scientific
- 5 literature.
- 6 So I'm suspecting that you all are already
- 7 thinking about what the alternatives are and collecting
- 8 some of the literature and being familiar with that in
- 9 that area. And what I find is some risk assessment
- 10 documents selectively omit stuff. And I'm never sure if
- 11 that's intentional or not. In some of the stuff that I
- 12 read oftentimes, particularly the government stuff, I'm
- 13 pretty sure it's not intentional. But and sometimes
- 14 those are really important. So that goes back to the,
- 15 "Is it important or not important?" for the overall
- 16 direction of where things are going to head for
- 17 management decision-making.
- 18 But it is remarkable how the same weaknesses
- 19 appear over and over again. And I know you've already
- 20 been through that process with staff in identifying some
- 21 of those themes, so I'm suspecting you'll be able to see
- 22 them again.
- Does that answer those?
- 24 PANEL MEMBER CARINGELLO: Yeah, that helps.
- 25 Yeah.

- 1 DR. WHITTAKER: Yeah.
- PANEL CO-CHAIR FONG: Elaine?
- 3 PANEL MEMBER COHEN-HUBAL: So, I'm not sure I
- 4 formulated my thoughts well. But I guess what I'm -- I
- 5 have not been involved in reviews, but I've peripherally
- 6 seen a lot of activity around how we're in the EPA
- 7 changing and improving the review process both in like
- 8 the IRIS program where IRIS, they're actually developing
- 9 the assessments. And then OPPT, the Office of Pesticide
- 10 and -- Pollution Prevention and Toxics, not Pesticides --
- 11 is really ramping up and revising their process.
- So for a couple reasons, both to improve, make
- 13 things flow more quickly, but also to really make sure
- 14 that to facilitate both the speed in which the review can
- 15 be done. But the sort of the breadth and rigor of that
- 16 review and then the documentation, right? So both
- 17 programs spent a lot of time or are spending a lot of
- 18 time right now really automating some of the resources
- 19 that they use to help them with the review. And then the
- 20 documentation of that review, so having these processes
- 21 in place, which is something that I think you'll grow
- 22 into. But maybe if you get access to a couple of those
- 23 people, which I think you are, and learn more about what
- 24 resources they are in-house sort of developing and using,
- 25 this first round of reviews will be sort of an

- 1 opportunity to.
- 2 So you have your AA guide. You have the
- 3 reviews of the AAs that you did where you sort of dive
- 4 into, so for that AA guide what's it mean on each of
- 5 those checklists, right? So you have like more detailed
- 6 questions that you were asking to sort of evaluate. So
- 7 you do have these evaluations that you've done. But what
- 8 resources would it help you to have on hand to be able to
- 9 answer those questions besides just kind of eyeballing
- 10 things, right? Based on your sort of way, sort of your
- 11 own professional expertise, right?
- 12 So I think more and more agencies are going
- 13 towards really being able to build in literature review,
- 14 so if what you're wanting to do is look at the
- 15 alternatives. So they come in the -- and Kelly made this
- 16 point -- alternatives and the factors, did they get those
- 17 right? And that's kind of like I think, really, that is
- 18 really the important thing you're wanting to get at,
- 19 right?
- 20 So they're going to throw at you these
- 21 alternatives well how do you know that that information
- 22 is good, right? So right away you can go to the
- 23 chemistry dashboard and get one level of information on
- 24 those chemicals, right? And how do you sort of automate
- 25 that or build that process in that we are going to go?

- 1 And we want what's out there on the properties of the
- 2 chemical, what's out there on the tox of the chemical,
- 3 what's out there on the occurrence? You know, what's out
- 4 there.
- 5 The limitation of that dashboard is that a lot
- 6 of the information in that is based on -- and a
- 7 commenter, a public commenter talked about CPDat -- the
- 8 information in both of those systems is drawn from sort
- 9 of these big resources. The literature is captured in a
- 10 very limited way in those resources, right? So then
- 11 having a second resource where you can really automate
- 12 and have at your fingertips access to the broader
- 13 literature.
- 14 So people talk about systematic review, but
- 15 it's more than just systematic review in environmental
- 16 health now means one thing in terms of how you evaluate
- 17 the studies. But the bigger bang for the buck for review
- 18 and regulatory agencies is going to be really knowing
- 19 that you've done a good job seeing what's out there very
- 20 quickly getting down to, "Is there anything on this
- 21 chemical?" Because especially as alternatives, right,
- 22 they are just going to be data-poor? Because if they
- 23 were data-rich and everybody knew they worked they'd just
- 24 be using them.
- 25 So I think that's going to be like one of the

- 1 really big issues in evaluating any of these things is
- 2 that we're looking at data-poor. And there's GreenScreen
- 3 and other things, but they're still really data-poor.
- 4 And there's a lot coming out every day on things. And
- 5 the value of that information is different, because there
- 6 are new data streams. So how you use that information is
- 7 going to be kind of a learning thing and you'll sort of
- 8 build that in.
- 9 But it's not a small amount of work to get
- 10 these kinds of processes in place. But the value of it
- 11 is going to be both that you know you can be more
- 12 confident that you know, that you have information you
- 13 need. And the documentation process will become
- 14 automated. And you won't run into this problem where you
- 15 need to use half of your 60 days just to document, right,
- 16 because it will be happening as you go along. So I think
- 17 this first couple rounds is going to be this huge
- 18 opportunity if you use it. So like with what IRIS is
- 19 doing and Kris Thayer is doing you can learn a lot about
- 20 what you should sort of be looking for this round in
- 21 terms of building that out. And I don't see how you
- 22 cannot make that investment.
- 23 And it isn't going to be as burdensome as it
- 24 was a few years back. I think there's so many more
- 25 things to build off of. So the IRIS tools that they're

- 1 using you'd be able to sort of build off. And OPPT is a
- 2 lot more behind the firewall. That process is not as
- 3 open. But a lot of what they're using is just bringing
- 4 things like the Chemistry Dashboard tailored to their
- 5 workflow behind a firewall.
- 6 So all right. And I think that those were kind
- 7 of my main points.
- 8 PANEL CO-CHAIR FONG: Elaine, thank you.
- 9 Let's see, any additional comments? Well, let
- 10 me just in that case just touch on --
- MR. LUAN: I'm sorry.
- 12 PANEL CO-CHAIR FONG: Oh?
- MR. LUAN: I'm not sure if it's appropriate for
- 14 me --
- 15 PANEL CO-CHAIR FONG: Yeah, Tony. Please.
- MR. LUAN: -- to say over here, but a lot of
- 17 these issues that are being brought up are very
- 18 encouraging for us, because we're trying to feel our way
- 19 through on how to review these AAs that are coming in,
- 20 methylene chloride especially.
- 21 But a lot of the topics that you guys mention
- 22 and the approaches that you guys mention are things that
- 23 we're sort of thinking about, so it's nice to have a
- 24 little bit of confirmation. You mentioned triage and we
- 25 were thinking about that as things coming in, as the AAs

- 1 come in, we will be looking at them holistically and we
- 2 will try to triage them very quickly. So I'm glad that
- 3 you're using that. And that's probably a good approach
- 4 for us to do that.
- 5 Mr. Caringello talked about the short
- 6 timeframes. And Anna Cross over here, one of our new
- 7 employees, she came up with the idea of having sort of a
- 8 concierge approach to the industry, the regulated
- 9 entities that we're working with. So we have assigned
- 10 staff to work with each of the responsible entities with
- 11 the AAs coming in. So we are maintaining contact, we are
- 12 trying to get an idea of what AAs area coming, and we're
- 13 trying to answer the regulatory questions. So we're
- 14 trying to get a jump ahead of the 60 days in terms of
- 15 working with industry and trying to get their
- 16 information.
- We have an outreach program that's been put
- 18 together by Melissa, so we're trying to outreach to the
- 19 industry to see that we've covered everybody, that
- 20 everybody that should have filed has filed.
- 21 Alternatives, Kelly Grant of our staff has
- 22 contacted others. Greg Morose, a researcher, has done a
- 23 lot of research on methylene chloride alternatives and
- 24 we've been reviewing it and we've been trying to get
- 25 ahead of the alternatives. So we know that there are

- 1 alternatives and there are limitations. We're trying to
- 2 get educated on that.
- We have GreenScreen training, that we've sent
- 4 most of our people to the introductory GreenScreen
- 5 training. I guess there's an intermediate training that
- 6 some of our people are going to be going to. And we're
- 7 trying to make a decision on the advanced GreenScreen
- 8 training, which seems to be very difficult. And we're
- 9 not quite sure whether that's appropriate or not. But
- 10 that's very encouraging to hear that that's something
- 11 that we should be doing and that's a good validation for
- 12 us.
- 13 You also mentioned the weakness on life cycle
- 14 analysis. And we're sending a couple of our staff, Anna
- 15 Gross, I'm sorry, Anna Gross and James Baker. They're
- 16 going to be taking Life Cycle training. So we're trying
- 17 to build up that expertise.
- 18 So I'm sorry, I just find this very encouraging
- 19 that even how we're feeling, to try to get our way
- 20 through this darkness, and to hear that some of the
- 21 approaches are somewhat things that other people have
- 22 used. So thank you for your input. I'm not sure if this
- 23 was appropriate, but I felt like it.
- 24 PANEL CO-CHAIR FONG: Absolutely, Tony. In
- 25 fact we encourage the staff to let us know when they have

- 1 specific questions that we can address.
- 2 PANEL CO-CHAIR MORAN: Can I say something
- 3 here?
- 4 PANEL CO-CHAIR FONG: Yeah, of course.
- 5 PANEL CO-CHAIR MORAN: Yeah. Helen Holder
- 6 wasn't able to be here today. And normally I wouldn't
- 7 talk to a committee member outside of the meeting, but I
- 8 scrupulously avoided talking to anyone else about this
- 9 topic, so that I could talk and get some comments from
- 10 Helen to relay. And I'm very much in sync with her on
- 11 this. Her main comment was, and recommendation to staff,
- 12 is the importance of benchmarking the AAs against each
- 13 other. That she's reviewed a lot of AAs and a lot of
- 14 other similar kinds of documents like I have, and
- 15 benchmarking is something that she's found to be really,
- 16 really valuable. And you all have that opportunity.
- 17 She has the same experience that I do. And
- 18 that opening up these kinds of documents and reading
- 19 them, pretty quickly you can tell if there's an agenda or
- 20 bias in them. And so some documents you open up and by
- 21 the time you're a third of the way through or sometimes
- 22 in the first couple of paragraphs you can see that it's a
- 23 difference of a particular thing or it's really aiming
- 24 towards one particular conclusion right from the very
- 25 beginning. And other ones are much more -- they may have

- 1 the same conclusion, but it's a really different approach
- 2 in the writing.
- 3 So and I asked her, "Can you give me examples
- 4 of the writing style?" And she said, "You'll just know
- 5 it, it'll leap off the page."
- 6 And she also points out that even with AAs,
- 7 with risk assessments -- we used to joke when I used to
- $8\,$ work on risk assessments 20 some years ago and I was
- 9 doing EIRs, so that's why I looked at lots of
- 10 alternatives -- that you could pretty much make anything
- 11 have any level of risk with the right approach to the
- 12 risk assessment. She feels that, she cautions that even
- 13 in the AA structure it's still possible to make almost
- 14 anything look good. And that's not what you want.
- 15 And that's why benchmarking is so important is
- 16 that the agency really is trying to do a very independent
- 17 evaluation. And not go with one particular agenda, but
- 18 really think through the science and the alternatives.
- 19 And recognize that there are going to be differences
- 20 among all the products. But benchmarking is going to be
- 21 very helpful. So she just kept saying, "Say
- 22 benchmarking, benchmarking, benchmarking, so I'm saying
- 23 that. Thank you.
- 24 PANEL CO-CHAIR FONG: Yeah, actually, that's
- 25 one thing that struck me and I'll touch on that also, is

- 1 that the AAs that you're going to be getting compared to
- 2 the ones that are publicly available. You know, you
- 3 mentioned Toxic Use Reduction Institute, TURI, and some
- 4 of the ones that were done through the EPA partnerships.
- 5 Those, when it comes to alternatives, we're looking at
- 6 the entire range of possible, viable alternatives.
- 7 Whereas the AAs that you're going to be getting may be
- 8 promoting a specific alternative that they are trying to
- 9 push, so that's just something to keep in mind.
- 10 Let me go to Mike and then we'll break.
- 11 PANEL MEMBER CARINGELLO: And I'll be quick.
- 12 PANEL CO-CHAIR FONG: No, take a minute.
- 13 PANEL MEMBER CARINGELLO: And so I just wanted
- 14 to make a comment on the benchmarking concept. And I
- 15 want to go back to what Jack had said before with the
- 16 NPEs, and I'm going back to my days when I was a chemist
- 17 and developing surfactants, is be careful when you're
- 18 benchmarking that you don't say, "This company in their
- 19 AA said these things would work as a potential
- 20 replacement for methylene chloride or any other
- 21 chemical," and just assume that the other companies
- 22 should have considered that as well. Because depending
- 23 on the variations in their formula those items might not
- 24 be viable. It could functionally not work. So I think
- 25 you do have to take that step back.

- 1 And I'm not saying this is what Kelly or Helen
- 2 was implying, but when you benchmark you need to
- 3 benchmark as, "Okay, they found things. Could this have
- 4 been applicable?" but don't hold them to saying, "This
- 5 company found this as the best alternative. Why weren't
- 6 you even considering it?" Maybe it's a discussion to
- 7 have, but don't benchmark them and expect them all to
- 8 have all of the same alternatives available.
- 9 PANEL CO-CHAIR FONG: Mike, thank you very
- 10 much.
- 11 So let's take a 15-minute break. And come back
- 12 and Kelly will start the next discussion.
- 13 PANEL CO-CHAIR MORAN: Thank you.
- 14 (Off the record at 10:16 a.m.)
- 15 (On the record at 10:33 a.m.)
- 16 PANEL CO-CHAIR MORAN: We ready? All right,
- 17 I'm calling back to the order the meeting of the Green
- 18 Ribbon Science Panel. And thank you all very much for
- 19 only extending the break by three minutes this time. So
- 20 that's a good record actually.
- 21 So the remainder of the time we have here we
- 22 can talk more about the AA process. And we ask the staff
- 23 if they wanted to give us some follow-up questions in
- 24 addition to these, so we may have a little more
- 25 discussion here since we've got that time opportunity.

- 1 And we can also, if we like, cycle back around
- 2 to any of the previous comments. One thing we might want
- 3 to check in is some of the metrics stuff again. Art
- 4 asked a really good question this morning about economic
- 5 benefits of this program to the state. It would be fun
- 6 to have a little chat about that for a minute.
- 7 But right now it seems like it would be good to
- 8 come back to the charge questions here. And see if folks
- 9 want to pull the thread on any of these? So we talked a
- 10 little bit about methodologies, approaches or strategies
- 11 that the panel recommends. Is there anybody who wants to
- 12 say anything else about that for the sort of rapid
- 13 review? Or the critical pieces of the AA? I think we've
- 14 spent a lot of time talking about those two things.
- Ann, you haven't said anything. And usually
- 16 you have a lot to say on these things, so I just wanted
- 17 to check in.
- 18 PANEL MEMBER BLAKE: I think I'm going to be
- 19 reiterating a lot of the points this morning, so I was
- 20 sort of holding back and wondering if that's a useful
- 21 thing or not.
- 22 PANEL CO-CHAIR MORAN: You always have
- 23 something useful to say, so I really don't want you to
- 24 hold back.
- 25 PANEL MEMBER BLAKE: Okay. Did you want to

- 1 finish your introductions before I do that?
- 2 PANEL CO-CHAIR MORAN: No. Those are the two
- 3 where we've really talked about, but we haven't -- we've
- 4 touched on Number 3 a little bit. But what are the key
- 5 elements, I guess we sort of talked about these things
- 6 all a bit. So I guess I'm looking to see if there's more
- 7 we can dive in on there. And if you want to say stuff
- 8 right now I think that would be very good. And then
- 9 maybe we check around with the rest of the panel about if
- 10 there's more you want to dive in on.
- 11 PANEL MEMBER BLAKE: I'm sure. I'll try and be
- 12 quick. I really appreciated Meg's presentation, because
- 13 I was sitting here thinking, "How on earth would I
- 14 classify how I do what I do?" So I thought I'd do a
- 15 little bit of context to see, so you can take it or leave
- 16 as how it's relevant to my approaches and how it's
- 17 relevant to what you're facing. Because what you're
- 18 facing is unique. But I did want to reiterate that you
- 19 do have more experience than you think you do. And trust
- 20 yourself on that.
- 21 And so I do a lot of, for different kinds of
- 22 clients, for NGO coalitions, companies and many others I
- 23 identify locations of hazards for particular products,
- 24 sentinel products or product categories. And then
- 25 summarize the pluses and minuses of available

- 1 alternatives. Or sometimes if I have that scope to say
- 2 what we would look for in a better alternative if it
- 3 isn't already on the market.
- 4 And then I also have some other small clients
- 5 that bring safer alternatives to the market. And I help
- 6 them articulate what their attributes are. So I think
- 7 the parallel that I see with your AA reviews is what's
- 8 relevant? And how do you articulate what's relevant
- 9 about a safer alternative?
- 10 And I would reiterate a lot of what was said
- 11 this morning about you already have a leg up on this,
- 12 understanding the process. Understanding the specificity
- 13 as Jack alluded to, if you're looking at specific
- 14 application, if you're looking, for example at a coating,
- 15 think about that particular application, what it's doing
- 16 on that specific substrate. You're probably going to
- 17 have that in the AAs that come to you for the methylene
- 18 chloride and its alternatives. So taking Mike's point
- 19 about benchmark, but don't hold that benchmark too
- 20 rigidly, because you're going to have different
- 21 applications. And so you have to have slight variability
- 22 in that benchmarking, because they're not going to be
- 23 directly comparable.
- 24 What else? I would reiterate also that you can
- 25 size up adequacy and inadequacy pretty readily, and

- 1 you'll get better at it. And also figuring out what's
- 2 relevant in each AA. Trying to think what else is useful
- 3 in this discussion.
- I would second on the issue of triaging. I
- 5 mean, I would also say that I'm constantly being asked to
- 6 take on new product categories. And not necessarily
- 7 knowing what the relevant standards are in those new
- 8 categories. Residential building is the Wild West, I'm
- 9 just warning you, if you ever happen to take that on.
- 10 And believe it or not you have more -- that's
- 11 my personal experience of you have more expertise than
- 12 you think that's relevant to a new area. You know how to
- 13 pick out what's a relevant standard, "What do I need to
- 14 know about it? What are they testing? Is that
- 15 appropriate to this alternative that I'm looking at?"
- 16 Some of the challenges I've seen in safer
- 17 alternatives that take a different, sometimes non-
- 18 chemical approach, is that the existing standards don't
- 19 necessarily apply. So keep an eye out for that. It may
- 20 or may not come up with methylene chloride. It may come
- 21 up with SPF. So for example I'm thinking about anti-
- 22 bacterials. If you're looking at kill rates, but you
- 23 have an alternative that's a structural alternative that
- 24 doesn't allow bacteria to stick to a surface the kill
- 25 rate really isn't a relevant standard. So that's one

- 1 that's come up for me.
- 2 And anything -- so things to look for, I guess
- 3 an excuse that I have seen in an AA, a publicly available
- 4 AA from Europe, is don't fall for the excuse of the
- 5 alternative doesn't exist because we don't manufacture
- 6 it. That may seem like an obvious one, but the fact that
- 7 it has been submitted in a public forum is -- just saying
- 8 that may happen.
- 9 Yeah, I think that's about the main things that
- 10 I'm thinking of, that you are better prepared than you'll
- 11 realize. And you'll learn on the go and that's okay.
- 12 Nobody has tried to do this before. So not to scare you,
- 13 no pressure, but. And we're here to support you as that
- 14 goes on.
- 15 ACTING DEP. DIRECTOR PALMER: Ann, can I ask
- 16 you a question on your thoughts?
- 17 PANEL MEMBER BLAKE: Sure.
- 18 ACTING DEP. DIRECTOR PALMER: So I know you've
- 19 thought a lot about functional use and substitution and
- 20 so --
- 21 PANEL MEMBER BLAKE: It's like Kelly's brake
- 22 pad saying. I can't go a meeting without saying
- 23 "functional use."
- 24 ACTING DEP. DIRECTOR PALMER: But in the
- 25 context of this question of well, what is a viable

- 1 alternative? And if I'm a methylene chloride person then
- 2 am I going to be looking at sandpaper or something in
- 3 between? I'm curious if you have thoughts about how we
- 4 would approach dealing with that kind of process. What's
- 5 a reasonable approach to say where are you -- how you
- 6 evaluate those alternatives in which some may be clearly
- 7 outside the capability of someone to do, but still an
- 8 alternative. And then how within our construct a way to
- 9 --
- 10 PANEL MEMBER BLAKE: So let me rephrase your
- 11 question, so how do you evaluate a potential alternative,
- 12 alternative that's like a non-chemical alternative, for
- 13 example, to the same functional use?
- 14 ACTING DEP. DIRECTOR PALMER: Yeah, that would
- 15 be one example. Or I'm just -- and sort of lessons
- 16 learned in looking at people who are -- most people look
- 17 at their product. And this concept of first is there a
- 18 drop-in that we could do?
- 19 PANEL MEMBER BLAKE: Right, which doesn't
- 20 always exist. Yeah.
- 21 ACTING DEP. DIRECTOR PALMER: But there's a
- 22 range of alternatives. And particularly if there's a
- 23 range of functional needs and applications that there's
- 24 how do you kind of sort that from when you start saying,
- 25 "Well this is outside of reasonable and should it be

- 1 considered or not?" I'm just from a practical, not --
- 2 PANEL MEMBER BLAKE: A practical point of view?
- 3 I don't know. That's where I find the biggest
- 4 challenges, because it makes me, it makes us all rethink,
- 5 "Well, how are we achieving this particular function?"
- 6 ACTING DEP. DIRECTOR PALMER: Mm-hmm.
- 7 PANEL MEMBER BLAKE: I think probably what
- 8 you'll find is that they will fall into certain
- 9 categories of approaches to a particular question about
- 10 functional use. And then it'll become more relevant what
- 11 the relevant factors are for each of those alternatives.
- 12 I hope that that's helpful.
- ACTING DEP. DIRECTOR PALMER: Yeah. Yeah, I
- 14 think it is.
- 15 PANEL MEMBER BLAKE: I think it's hard to talk
- 16 about in the abstract. It would be, yeah.
- 17 ACTING DEP. DIRECTOR PALMER: It is, yeah.
- 18 PANEL MEMBER BLAKE: Yeah.
- 19 ACTING DEP. DIRECTOR PALMER: Understood.
- 20 Thank you.
- 21 PANEL CO-CHAIR MORAN: All right. Other folks
- 22 who wanted -- Elaine could I just --
- 23 ACTING DIRECTOR WILLIAMS: Yeah. Oh, I'm
- 24 sorry.
- 25 PANEL CO-CHAIR MORAN: -- could I kind of

- 1 redirect that question to Meg a little bit? Because I
- 2 know you worked on the boat paint alternatives analysis.
- 3 And I know this is a big point of discussion. And I
- 4 wondered if you had any thoughts on that particular
- 5 question on functional use and the gaming of functional
- 6 use.
- 7 DR. WHITTAKER: Right. Well, I think you're
- 8 going to be receiving documents where they're advocating,
- 9 they've already made up their mind about probably the
- 10 alternative. And they're going to go through and
- 11 identify potential alternatives and the functional use.
- I tend to look at, "Does it seem plausible
- 13 based on my little bits of scientific knowledge?"
- 14 Especially if they try and say, "Well, we can't use
- 15 these." Is it explained why? Does it seem
- 16 scientifically reasonable from that? And you've got
- 17 chemists on your staff and engineers. And they have more
- 18 expertise than you do right now.
- 19 So you'll be receiving a submission and you're
- 20 going to have to take some of what they say on face value
- 21 but dig into it. And that's what I do. I try and figure
- 22 out, pull the thread or I Google terms to see is this
- 23 really true? Not that you want to believe anything that
- 24 you Google, but -- don't Google your name -- but that's
- 25 kind of what we do to figure out for functional

- 1 alternatives.
- 2 And it's the same issue in looking at
- 3 performance testing when they're using in-house
- 4 laboratories I want to see pictures and especially if
- 5 there's no test method. Like you have USEPA Safer Choice
- 6 will allow for certain products to be tested in
- 7 performance testing if there's no real test method. But
- 8 believe me, if it's an in-house laboratory and it's a
- 9 company we've never heard of, and I've never audited the
- 10 company and their lab, I want to see pictures. I want
- 11 overkill on details before I believe it.
- 12 And not that everyone has to run to B.V. or
- 13 Intertek or any of the other ones. Lots of people have
- 14 good in-house labs. But ask, "Is it 17-025 accredited?"
- 15 If you don't know what that is Google that. Probably any
- 16 chemist does in here. But it's challenging because
- 17 people are going to try and spin a tale too, for certain
- 18 people. Not all submissions. I think like you said,
- 19 "Get that baseline, get that fast submission," and then
- 20 try and set the pace for everybody else, because you're
- 21 going to get some winners I know. And the other people
- 22 are going to have to submit to that level.
- 23 PANEL MEMBER BLAKE: Can I add to that, because
- 24 that example you brought up made me remember. But you'll
- 25 see you may get presented with alternatives that look

- 1 like a functional, a different answer to the functional
- 2 use, but it's actually just a tweak of the chemistry.
- 3 But it can be hidden in a different way. I'm thinking
- 4 boat paint particularly is minimizing the toxic Chemical
- 5 of Concern, but wrapping it in other stuff. It turned
- 6 out to be problematic.
- 7 PANEL CO-CHAIR MORAN: And I want to build on
- $8\,$ what Meg said about study design. There are two kinds of
- 9 study designs. There's the kind that's really
- 10 scientifically done in a way that's going to provide
- 11 information about various alternatives or situations and
- 12 so forth. And there are other study designs that are
- 13 fundamentally flawed by some element of the design that
- 14 then lead to not providing the actual information. And I
- 15 don't think the DTSC is going to either have the time or
- 16 means to evaluate every study design in everything that
- 17 is submitted.
- 18 But particularly in areas like we were just
- 19 talking about, about the effectiveness testing, you can -
- 20 examining the study design is going to be really
- 21 important based on the chemistry and all the other things
- 22 that are going on there. For anything that's going to be
- 23 absolutely critical in bringing in or leaving out a
- 24 relevant factor or bringing in or leaving out an
- 25 alternative.

- 1 So those kind of key -- there'll be a certain
- 2 number of studies. My guess is that it's just going to
- 3 be a few dozen. But at most, and maybe only a few, that
- 4 are going to be really important where you really want to
- 5 think about that.
- There's a lot of gaming of study design.
- 7 Sometimes it's just complete lack of understanding and
- 8 particularly, I've seen this a lot in environmental fate
- 9 studies. So they use the wrong particle size, they use
- 10 the wrong fake rainstorm, they use the -- there's stuff
- 11 that's just so obvious if you come in from a different
- 12 field. But a lot of time folks who were designing those
- 13 just don't know. They've never done that kind of stuff
- 14 before and so you get these really weird or wrong
- 15 results.
- 16 That's something that is going to take some
- 17 thought in pulling apart. But it only really needs to be
- 18 done on those things that are critical on a yeah or nay?
- 19 PANEL MEMBER BLAKE: Yes. I would second that.
- 20 Are they asking the right questions in the study,
- 21 relevant questions?
- 22 PANEL CO-CHAIR MORAN: Yeah.
- 23 PANEL MEMBER ZARKER: So this is Ken. One of
- 24 the things I'm hopeful that folks are approaching this in
- 25 the spirit of the law as opposed to sometimes the letter

- 1 of the law. And I think that we'll probably get some
- 2 good or at least I'm hopeful that we're going to get some
- 3 good information.
- 4 My question is around sort of the issues that
- 5 come up around costs and availability for these
- 6 alternatives. And sometimes when you have something that
- 7 may hold a lot of promise, but it's a niche market and
- $8\,$ it's not at the scale that may be needed to really
- 9 transform a particular product category. So I was
- 10 wondering if there might be some feedback on that,
- 11 thinking about that.
- 12 And then taking it to the next step, which is
- 13 maybe this regulatory response or regulatory action, how
- 14 that issue we're going to have to deal with plays into
- 15 some of the thinking in terms of when we talk about
- 16 innovation and advancing these kinds of things. So I've
- 17 been just thinking a little bit about that this morning
- 18 and how we -- and maybe the staff have thought about that
- 19 a little bit as well.
- 20 PANEL CO-CHAIR FONG: Go for it.
- 21 ACTING DIRECTOR WILLIAMS: So, yeah. I do
- 22 think that we're going to be in situations where
- 23 something's not ready for primetime. And this is where I
- 24 tend to look at Europe and look at REACH. And when they
- 25 do an analysis of alternatives and they set a timeline

- 1 for revisiting the analysis of alternative, if we were to
- 2 couple that kind of approach with the regulatory response
- 3 for Green Chemistry Funding then I think we're getting in
- 4 the neighborhood of practical solution to something that
- 5 has promise, but isn't fully proven, isn't known to be
- 6 scalable.
- 7 ACTING DEP. DIRECTOR PALMER: I might just add
- 8 that in going around talking to industry folks of
- 9 concern, I remind folks that we're not pre-determining an
- 10 outcome. So the course run of this process is doing the
- 11 AA and making something safer. And that might be
- 12 incremental. We might find the silver bullet that has
- 13 broad application. We might find certain applications
- 14 where there is a better alternative than not. It's
- 15 really going to depend on what comes in the door. And if
- 16 you just look at the regulatory responses those are just
- 17 one of the outcomes that we have.
- 18 The manufacturers have all kinds of outcomes
- 19 that they could suggest that would potentially move
- 20 innovation forward, making it safer. And I'll point to
- 21 this, our colleagues in the spray foam industry, when we
- 22 picked spray foam systems with MDI we recognized that
- 23 there really wasn't something off the shelf or even close
- 24 to dealing with those chemistries of those polymers for
- 25 making foam. But we also noted there are probably things

- 1 that could be done to protect the workers. And there are
- 2 probably advances that the industry could move towards,
- 3 but not a drop-in replacement to MDI that would be
- 4 equivalent. So it's important that we, this process
- 5 moves everything forward. And that could look like a lot
- 6 of different things.
- 7 PANEL MEMBER ZARKER: Okay.
- 8 PANEL CO-CHAIR MORAN: So you look like you're
- 9 about to say something. Go ahead, Jack.
- 10 PANEL MEMBER LINARD: I'm waiting for this
- 11 discussion to end, because I just had a couple of
- 12 comments. One, on Questions 3 and 4, 3 from a
- 13 manufacturer's point of view seems to imply an inherent
- 14 bias. I think you need to be very careful not to express
- 15 that, that you think everybody is trying to protect the
- 16 current market. So you may have that internally and
- 17 innately, but the bottom line is I don't think you should
- 18 express it. And to say you're just trying to hide
- 19 something or protect the status quo., I just think it
- 20 doesn't look good to say that, "Oh, you're just doing
- 21 this to protect what you've got." So I just think just
- 22 watch out for the words you use.
- 23 And Number 4, "What other types of things can
- 24 you do?" This is the Safer Consumer Products Regulation
- 25 and I'm sure there are products on the shelf, which are

- 1 not methylene chloride yet are paint strippers. Go to
- 2 Home Depot, go to Lowe's, go to your local hardware
- 3 store. See what's on shelf, because those products are
- 4 not going to be submitted for an AA, but they may still
- 5 exist.
- 6 So you can do your homework in advance. You
- 7 are a consumer as well. Take advantage of it and become
- $8\,$ a consumer and see what else is out there. Because I
- 9 mean I said yesterday I do lot of shopping at stores I
- 10 normally wouldn't go into just to find out what's out
- 11 there? And that's a critical piece of being able to
- 12 understand the market is to say, "Yes there are methylene
- 13 chloride paint strippers. But there are other products
- 14 out there, which make similar promises." So I think it
- 15 just prepares you better for what you're going to get.
- 16 PANEL CO-CHAIR MORAN: Other comments from the
- 17 panel about any of these topics? I've got a couple
- 18 things I just forgot to say.
- 19 One of the clues for me that there's something
- 20 wrong with an AA is that it has conclusory statements
- 21 without sort of citations or thoughtful discussion. Karl
- 22 has been saying, "Show your work," since the beginning.
- 23 And I read tons of risk assessments where there are
- 24 conclusory statements. And I find them super-annoying.
- 25 But once again, I parse out what matters and what doesn't

- 1 and go with that. And some of those conclusory
- 2 statements are wrong, but they don't matter.
- But that, to me, as soon as I start reading
- 4 things that -- you might see the conclusory statement in
- 5 the summary and then it's backed up by "show your work"
- 6 later on, but where you start seeing a lot of conclusory
- 7 statements that for me is a red flag. The person who
- 8 prepared that did not do a thoughtful job and wasn't
- 9 doing it.
- 10 And the other thing, sentinel exposures are
- 11 kind of something that I think are becoming part of the
- 12 scene here for necessity reasons, but they need to be
- 13 very carefully chosen. So I've actually seen many
- 14 examples where of one exposure is assumed to be sentinel
- 15 and the most important thing and is actually wrong. It
- 16 is a completely different thing that's going to be the
- 17 greatest exposure or going to cause the greatest harm.
- 18 So sometimes the greatest exposure doesn't go to the
- 19 endpoint where the greatest harm can occur. So a much
- 20 smaller exposure in a different media or location or
- 21 exposure pathway can wind up being much environmentally
- 22 relevant.
- 23 So that's a very chemical-specific kind of
- 24 thing. My great example of that is for the pyrethroid
- 25 insecticides, where most of them land on surfaces and

- 1 stay there. But it's only less than 1 percent of what's
- 2 used that actually matters. And the place it matters the
- 3 most is if it lands on impervious surfaces and gets
- 4 washed into creeks where tiny, tiny little concentrations
- 5 are harmful. So if you're looking at the sentinel you're
- 6 following it to the impervious surface and you might be
- 7 thinking about plant uptake or mammalian exposure or some
- 8 other kind of thing and you're totally missing the thing
- 9 that actually matters, which is that we're seeing
- 10 toxicity throughout aquatic ecosystems in urban areas in
- 11 California due to this.
- 12 So it's pulling the thread a little bit,
- 13 thinking through that concept of where is the sentinel
- 14 exposure the right thing? Where do we really need to
- 15 look more deeply at what is the exposure that matters?
- 16 And that's a combination of fate, transport and toxicity
- 17 data. And thinking all of that through is important.
- I don't think that's going to be a huge thing
- 19 here for the first couple that you've got. And I don't
- 20 think there's a mystery in this. But it's just something
- 21 I want to call out, because I've seen a lot of people
- 22 using Don Mackay's kind of little box and say, "Oh it's
- 23 where it And then we'll look at it there." And it's
- 24 just -- and where most of it is what matters. And that
- 25 just doesn't work in, particularly, environmental

- 1 endpoints. So a couple other thoughts.
- If there aren't comments on this, I guess I
- 3 wanted to turn to staff and see if you all had additional
- 4 questions.
- 5 Oh, I'm sorry, Ken's got one more.
- 6 PANEL MEMBER ZARKER: Oh, yeah. Thank you,
- 7 Kelly. I just wanted to follow up, a follow-up question.
- 8 You brought the issue of citations. And I wanted to get
- 9 some of your thinking around that, because there may be
- $10\,$ some AAs that are more complex than others. And so I'm
- 11 wondering about the use of citations. Is it to make it
- 12 more defensible, to make it more -- You know, sometimes
- 13 I see citations in documents and some of them just go on
- 14 and on and on. And I'm starting to wonder like, well
- 15 what's the right balance here in terms of that level of
- 16 documentation? And so, trying to better understand your
- 17 thinking a little bit about around that, what's the right
- 18 balance for that?
- 19 PANEL CO-CHAIR MORAN: Well, that's a --
- 20 PANEL MEMBER ZARKER: And maybe others might
- 21 want to?
- 22 PANEL CO-CHAIR MORAN: Yeah. I'm thinking
- 23 Elaine and some other folks here might have some thoughts
- 24 on that. I mean it just generally when I'm reviewing
- 25 something as a scientist if somebody said something and

- 1 there's nothing to back it up, immediately I'm
- 2 suspicious. That's just the normal scientist peer
- 3 review.
- 4 But it's not necessarily the number of
- 5 citations it's the quality that really matters. And
- 6 again, it's the importance of that endpoint. In some
- 7 ways you want every sentence in the whole thing to be
- 8 cited. And of course that's not really where you're
- 9 headed. It's really every major concept having backup to
- 10 support the "showing your work." So I --
- 11 PANEL CO-CHAIR FONG: Can I just, Kelly?
- 12 PANEL CO-CHAIR MORAN: Yeah.
- 13 PANEL CO-CHAIR FONG: So how I use citations in
- 14 addition to the points that Kelly makes is actually it
- 15 helps me understand the author's thinking process.
- 16 PANEL CO-CHAIR MORAN: Xiaoying and then Ann.
- 17 MS. ZHOU: Yeah, Ann first and then me.
- 18 PANEL MEMBER BLAKE: I just want a point of
- 19 clarification. You were talking about sentinel
- 20 exposures?
- 21 PANEL CO-CHAIR MORAN: Uh-huh.
- 22 PANEL MEMBER BLAKE: And I know I mentioned the
- 23 word sentinel, so I just wanted to be clear that I was
- 24 using it in the context of sentinel products. That this
- 25 was a way for a retailer with a vast number of products

- 1 to figure out which were the ones -- and exposure was
- 2 part of it, but it was who is this product being marketed
- 3 to? Was there a vulnerable population involved? So it
- 4 wasn't quite the same concept. I just want to --
- 5 Xiaoying?
- 6 MS. ZHOU: Yeah. Just to follow up that
- 7 citation question. And for some alternatives we find out
- 8 there's a lot of, maybe not data-poor, but it's a data
- 9 breach. But there's conflicting information and they're
- 10 all published in those peer review journals. And so the
- 11 staff feel it's kind of challenging to really support
- 12 their statement or they just are like a (indiscernible)
- 13 because we are not required to use the weight of the
- 14 evidence and asserts. (phonetic) And so if there's any
- 15 tape to advise on those kinds of things?
- 16 PANEL CO-CHAIR MORAN: Yeah. That's something
- 17 I see a lot. And I actually have a lot of trouble with
- 18 that, trying to figure out which and where. Benchmarking
- 19 is very helpful, so if there's a lot of people looking at
- 20 the same chemical, being able to see what all the sources
- 21 are. Obviously, your own literature review is important.
- 22 And then, really, if it's a critical -- so not
- 23 every factor is going to -- not every relevant -- in all
- 24 of the data that you're going to get not everything is
- 25 going to be super-important in making the decision, so

- 1 focusing in on those that are. But this is a real
- 2 challenge. Then if it's a really important endpoint,
- 3 they are looking at the different studies and actually
- 4 evaluating their qualities, is often important.
- 5 So there are I have more than once looked at a
- 6 whole set of data and there's different reasons that
- 7 things can be wrong. So and folks here can talk about
- 8 right or wrong or it's just the best. And there's a lot
- 9 of different approaches.
- 10 The USDA ARS came up with a methodology for
- 11 reviewing various studies and an approach for doing that.
- 12 The EPA's ECOTOX Database, they also have a way of
- 13 deciding if studies are good or bad. And of course,
- 14 there's very -- this is another one. I keep looking at
- 15 Elaine, because I know she knows more about this than I
- 16 do -- but it's definitely a struggle.
- 17 ACTING DIRECTOR WILLIAMS: Yeah, if I could
- 18 chime in on that, which is we've been talking a lot in
- 19 the program about systematic review. And one of the
- 20 things that's so important for a systematic review is to
- 21 really decide what's the data quality of a particular
- 22 citation. And so I think we're going to continue that
- 23 discussion within the program with some of the experts
- 24 that have looked into this.
- 25 For instance, Kris Thayer, who is the head of

- 1 IRIS will be visiting OEHHA. She's doing essentially a
- 2 three-week residency starting now. And so she's going to
- 3 spend some time with Safer Consumer Products and this is
- 4 a great question to ask her as part of that conversation.
- 5 Elaine?
- 6 PANEL MEMBER COHEN-HUBAL: Oh, you know, I
- 7 quess --
- 8 PANEL CO-CHAIR MORAN: Go ahead, Elaine. I'm
- 9 picking on you.
- 10 PANEL MEMBER COHEN-HUBAL: Okay. I started
- 11 thinking about too many things at once, I think, because
- 12 the exposure I think that I always feel like exposure is
- 13 the weak link. And not just it -- and mostly because it
- 14 puts me in as an exposure scientist, and I'm not a risk
- 15 assessor. But I consistently feel very uncomfortable
- 16 with the way we do exposure assessment. And that it's so
- 17 data-poor the way that we do it, right? And so in
- 18 addition to evaluating evidence it's very difficult,
- 19 right? So in lieu of NHANES and biomonitoring and
- 20 occurrence information for -- again, a lot of the
- 21 alternatives may likely be data-poor, right? And
- 22 thinking about the way that life cycle assessment
- 23 currently does impact.
- So of course, there's so many opportunities
- 25 here to sort of just move the field forward and build

- 1 capacity and lead the way and all these great things.
- 2 But in the meantime how you evaluate current evidence, I
- 3 mean, you can't hold people to a standard based on what's
- 4 available today and what the tools are today.
- 5 But I do think, and you didn't ask me about
- 6 exposure assessment, but I do think it's going to be
- 7 really important that at each stage of the chemical
- 8 product life cycle that there is thought put into what
- 9 are the exposure scenarios that are most important. And
- 10 how those may or may not change what that comparison will
- 11 be for the alternatives and stuff. So reviewing that,
- 12 it's going to be challenging only because I don't think
- 13 there are really good standards.
- But I think that's something again that as long
- 15 as you're sort of really documenting what you think today
- 16 is important to be looking for. So if the most important
- 17 thing to be looking for is that they've gone through that
- 18 process and that process looks thoughtful, that's
- 19 reasonable right?
- 20 But in terms of having some literature to back
- 21 that up I think it's important. I think there are more
- 22 and more everyday opportunities where people are doing a
- 23 lot more work in these areas. And I just continue to
- 24 believe that it's going to be very hard.
- To me, the 60 days, when I think about what

- 1 people in regulatory agencies are currently -- what
- 2 questions and what kinds of documents they're trying to
- 3 assess in 60 days and how challenging that is. And then
- 4 what you're doing is like that order of magnitude in
- 5 terms of the level of comparisons and information. And I
- 6 mean it's just 60 days just blows my mind, so yeah, it
- 7 matters that things are tied to evidence.
- 8 But at the end of the day the standards for
- 9 that evidence, I think you'll be moving the field forward
- 10 if you're able to, as you're moving along and learning in
- 11 this process, if you're able to say, "We see that you've
- 12 pointed to where there's a study. It's in vitro." Or
- 13 you know that it's not traditional, it's not whatever
- 14 limitations, but there's I think it's going to be really
- 15 helpful to look at sort of the ranking and things that
- 16 they do in IRIS for hazard.
- 17 And where I was saying we're -- I'm thinking
- 18 about trying to -- I'm not thinking about -- I'm trying
- 19 to do something similar on exposure for a set of
- 20 compounds. And I'm seeing so how would you look at the
- 21 literature to find evidence, to capture evidence of
- 22 particular exposure pathways or particular compounds?
- 23 And what does that look like and then how do you evaluate
- 24 those manuscripts?
- So, one will look like there's a population and

- 1 the occurrence in particular exposure media is measured,
- 2 and serum levels are measured, right? So now you've got
- 3 like a high level. And assuming that the study design
- 4 looks good and it's representative of that population,
- 5 right. So to get to that standard is going to be almost
- 6 impossible in the literature for almost everything, so
- 7 then what would the next two, three, four levels look
- 8 like? And so we're just doing this now and if anybody
- 9 knows that this has been done before, please let me know,
- 10 because I would rather borrow. (Laughter.)
- 11 But anyway I'm not sure I even answered your
- 12 question, just a lot of meandering thoughts.
- 13 PANEL CO-CHAIR MORAN: I think it's harder for
- 14 exposure than it is for more traditional endpoints. I
- 15 mean, it's just like, yeah.
- 16 PANEL MEMBER COHEN-HUBAL: And I agree that in
- 17 many ways it may or may not be as important as the
- 18 hazard, but because you're moving to looking at the life
- 19 cycle and looking at this. Again, it's the analysis and
- 20 the conclusions and the decisions are only going to be as
- 21 good as the weakest link. And so I just think it's going
- 22 to be really -- and nothing -- I find it disconcerting
- 23 when I read risk assessments.
- 24 And I've been on the -- I work on Health
- 25 Canada's Chemical Management Program on their Science

- 1 Committee. And one of the very first things they brought
- 2 to us was something about uncertainty. And I can't
- 3 remember it, because what we ended up doing was just
- 4 changing their question. (Laughter.)
- 5 Because in my mind nothing unnerves me more
- 6 when people just say "There's uncertainty here, there's
- 7 uncertainty there. And it's up here, down there." And
- 8 they just write it all down. And I don't see how a
- 9 decision maker can use that information. I mean, to me
- 10 it is possible to quantify uncertainty even if it's eight
- 11 orders of magnitude.
- But I think when people are going to make
- 13 decisions the most important thing in a decision is that
- 14 this is the key uncertainty. If we had information there
- 15 it might change our decision. And I don't know, that's
- 16 what I would look for. I mean if you get an assessment
- 17 back and somebody has really been able to nail down,
- 18 "These are the three key uncertainties. And if we knew
- 19 more about this, this and this, if we could go measure
- 20 this, this and this we might come up with a different
- 21 answer," that would just be a game changer.
- 22 PANEL CO-CHAIR MORAN: Yeah.
- You're up, Mike.
- 24 PANEL MEMBER CARINGELLO: Sure. And I was not
- 25 racing to put my test there before you. I knew you had

- 1 been called. It was just I thought of something and I
- 2 wanted to --
- 3 But I'm going to echo some of the themes that
- 4 Elaine was talking about. And I've expressed my dismay
- 5 over the 60 days, it's a big challenge. And then
- 6 documenting what you do? I think it's really key with
- 7 how you assess these AAs that you are very consistent
- 8 with the different REs. You know, when their AAs come in
- 9 or however they flow, if it's through a trade
- 10 association, however, that you're consistent across the
- 11 board for a priority product, but then for future
- 12 priority products as well.
- 13 And just a thought I had based on what Meredith
- 14 was saying about quality of citations. I really think
- 15 now is the time if you haven't already done it, and you
- 16 probably have, but before these AAs come in develop some
- 17 sort of method where -- because you're going to have a
- 18 bunch of citations coming in. And you're going to look
- 19 at each and every one of those and assess the quality, so
- 20 have a method where in the current set of AAs that are
- 21 coming in, you're sharing those assessments. Maybe have
- 22 if one person's done it, not everyone needs to do it.
- 23 That might shave some time off.
- 24 But also make sure that you historically keep a
- 25 record of why you assess that citation that way. So that

- 1 when someone comes up with that as an alternative 12
- 2 priority products down the line because there is a
- 3 similar application, that you don't have to go back and
- 4 re-review the citation. And you're consistent with how
- 5 you evaluated it. I just think it's just kind of along
- 6 Meg's line of tips maybe. We've run into that all the
- 7 time of, "What did we do? How did we justify that?" And
- 8 I think it's important.
- 9 ACTING DIRECTOR WILLIAMS: And I have to give
- $10\,$ props to staff -- sorry to interrupt -- but because they
- 11 do spend a lot of time figuring out how to document
- 12 things as they go along. Because we make decisions every
- 13 step of the way. And trying to, you know, if somebody's
- 14 not in the room we want them to be able to go back and
- 15 say just what was the basis for what we did. And so that
- 16 certainly is built into the chemical product evaluation
- 17 process for prioritization. And I think we need to adopt
- 18 that same mindset for the AA review. How are we going to
- 19 document those things? What systems can we put in place?
- 20 PANEL MEMBER COHEN-HUBAL: I was just going to
- 21 say this is where your time with Kris Thayer could be a
- 22 game changer. I don't know what your internal sort of IT
- 23 looks like for being able to capture and really easily
- 24 document and access this kind of stuff, but that that's
- 25 what they really spent a huge amount of time on it in the

- 1 last couple of years. And I don't see how you're going
- 2 to do this consistently and well and efficiently and feel
- 3 really, really good. And have your regulated community
- 4 feel really good if these kinds of tools aren't brought
- 5 in to your program.
- 6 PANEL CO-CHAIR MORAN: Right. And I think a
- 7 lot of us have the experience where there's, as certain
- 8 decisions come to down to a small array of studies, they
- 9 keep reappearing, I keep seeing the same things and the
- 10 same flawed studies cited over and over again. There's
- 11 one that drives me crazy that's about zinc and run-off
- 12 and it's near a hazardous waste incinerator. So there's
- 13 the time, more zinc and the run-off from the routes there
- 14 because of the air duct position in the area. And so
- 15 it's completely flawed. And people misunderstand that,
- 16 because it's not clear in the paper. You have to kind of
- 17 pull the thread on it, "Why is this paper different than
- 18 all the other ones?"
- 19 And once your staff have done that then you'll
- $20\,$ get that. And you'll keep seeing these same set of
- 21 studies over and over again. And to the extent that you
- 22 can clarify that and even clarify that with the industry
- 23 if folks share stuff with you ahead of time, that these
- 24 studies have some specific flaws and these studies seem
- 25 to be of higher quality. That's really helpful.

- 1 So did you want to say something here?
- 2 ACTING DEP. DIRECTOR PALMER: Well, I was just
- 3 going to ask Elaine to maybe clarify it, because she had
- 4 mentioned earlier about this automation of process with
- 5 reference to literature review. But was that also for
- 6 decision making?
- 7 PANEL MEMBER COHEN-HUBAL: There and so and
- $8\,$ again I'm just starting to learn a little bit about the
- 9 tools that the IRIS program has brought in and tailored
- 10 to their processes. And again, they're literally doing
- 11 this now with each assessment that they're working on.
- 12 But they're at the point where there's really a "there"
- 13 there. But they are using it not just to access the
- 14 literature, and I mean broadly the literature, okay? Not
- 15 --
- 16 ACTING DIRECTOR WILLIAMS: Thousands of
- 17 citations.
- 18 PANEL MEMBER COHEN-HUBAL: Right. Okay. Not
- 19 just what's in PubMed, but broad access to literature and
- 20 gray literature and whatever else. But then they're also
- 21 using it to document how they select literature and
- 22 evaluate literature. And then they're also using their
- 23 systems down the line, that kind of thing down the line
- 24 that they're using to show how they use things in their
- 25 assessments and in their decisions. So it's pretty

- 1 remarkable, I think, where it's going.
- 2 But then the workflows have some automation to
- 3 them. And the record-keeping is very clean.
- 4 ACTING DEP. DIRECTOR PALMER: Great. Thank
- 5 you. So we'll ask Kris Thayer about the "there, there."
- 6 (Laughter.)
- 7 PANEL MEMBER COHEN-HUBAL: So it's lot of work.
- 8 PANEL CO-CHAIR MORAN: So Meg's had her flag up
- 9 for a while and then Jack.
- DR. WHITTAKER: We use the ToxRTool to, which
- 11 is really simple. ECVAM made it and EPA uses it, so I'm
- 12 sure Kris Thayer uses it too, to rate studies for
- 13 reliability. And it's an easy way to keep track too, of
- 14 when you're going to see the same chemical and multiple
- 15 people are going to be evaluating it.
- 16 So I can send over an example of like it filled
- 17 out for -- we use it also when we pick surrogates -- but
- 18 it's a freely downloadable Excel workbook. And EPA likes
- 19 it and I'm sure they can give you feedback on it. You're
- 20 not always going to need to use it, but it really helps
- 21 if someone gives you oodles of studies to try and -- or
- 22 of a million alternatives. And you can only look at a
- 23 couple of data points at a time, or at least I can. I
- 24 shouldn't say you. But I need to write it down and see
- 25 it, so it's a nice little tool to try and assess

- 1 reliability when you're trying to figure out which
- 2 alternative is really the best.
- 3 And you're also -- what's hard for me is the
- 4 scariest part was seeing an alternative is going to have
- 5 some type of hazard. And ideally it won't be a Chemical
- 6 of Concern, but you have to let go that there is nothing
- 7 that's without -- everything is hazardous. And that
- 8 that's okay depending on the situation of exposure.
- 9 I don't know, that was hard for me. I wanted
- 10 hazard-free and you're never going to get that. Yeah, so
- 11 I'll send over that.
- 12 ACTING DEP. DIRECTOR PALMER: Thank you.
- 13 PANEL MEMBER COHEN-HUBAL: That's a nice little
- 14 quick tool and it's Excel-based, so you don't have to buy
- 15 a \$100,000 piece of software.
- 16 PANEL CO-CHAIR MORAN: Okay. Jack?
- 17 Thanks Meg.
- 18 PANEL MEMBER LINARD: Just a quick question, or
- 19 a comment more. Industry provided a lot of data to ECA,
- 20 the European Chemicals Agency, but that is going to be
- 21 held confidential. Will the Department be willing to
- 22 accept ECA's conclusions without being and having access
- 23 to those studies, because those studies are being held as
- 24 business-confidential. Same goes for Health Canada and
- 25 the Chemical Management Plan.

- I don't know what your answer is, but I think
- 2 it's important to be very clear that you will or will not
- 3 or under what conditions you might accept their
- 4 conclusions, because it's you're trusting them to do the
- 5 right thing, I hope.
- 6 ACTING DIRECTOR WILLIAMS: I'm not going to
- 7 answer that, because (indiscernible) (Laughter.)
- 8 PANEL CO-CHAIR MORAN: Yeah, go for it.
- 9 PANEL MEMBER COHEN-HUBAL: I'm just saying that
- 10 all I'm going to say is I'm going back to your three
- 11 pillars. And you're leading the way in building capacity
- 12 on the opportunity you have to really encourage more open
- 13 and transparent access to information. And I appreciate
- 14 that companies have a really important proprietary needs
- 15 for certain information. But again, your program has
- 16 some opportunities and on this that's all I'm going to
- 17 say.
- 18 PANEL CO-CHAIR MORAN: I'll point out that
- 19 EPA's Pesticides Office, instead of making the full
- 20 report public they do a detailed analysis and have a data
- 21 evaluation record, so it doesn't make the report
- 22 available for someone to take and submit to some other
- 23 country. But there's way more transparency on the
- 24 evaluation than just the result, which is what I've seen
- 25 with ECA stuff. So there are a variety of approaches out

- 1 there to provide transparency and the Department really
- 2 needs to figure that out.
- Meg, are you wanting to weigh in on this one or
- 4 is that just still from before?
- DR. WHITTAKER: Oh, sorry.
- 6 PANEL CO-CHAIR MORAN: That's okay, I just
- 7 wanted to check and see.
- B DR. WHITTAKER: I just want to see if you're
- 9 looking at me. (Laughter.)
- 10 PANEL CO-CHAIR MORAN: Yeah. I'm starting to
- 11 get hungry, so --
- 12 PANEL MEMBER LINARD: And that was the reason
- 13 for my question is I think you need to decide early on
- 14 what you are willing to accept or not accept.
- 15 ACTING DEP. DIRECTOR PALMER: Well, just a
- 16 reminder that the regulations require that that
- 17 information be submitted to us on the basis of their AA.
- 18 PANEL MEMBER LINARD: Right.
- 19 ACTING DEP. DIRECTOR PALMER: And that we can
- 20 and will protect CDI. The process, so the responsible
- 21 entity has some decisions to make about what they want to
- 22 provide to us. And I think that out of the box we're not
- 23 going to just say, "Because ECA decided it was okay we're
- 24 going to say it's okay." It's going to take more than
- 25 that.

- 1 PANEL MEMBER LINARD: And really, that's the
- 2 type of statement I think is important to make it clear.
- 3 ACTING DEP. DIRECTOR PALMER: I mean, I think -
- 4 is that okay?
- 5 PANEL CO-CHAIR MORAN: I'm fine with that.
- 6 ACTING DEP. DIRECTOR PALMER: Yeah.
- 7 PANEL MEMBER LINARD: Because if you're part of
- 8 the SIEF in Europe and you submitted some data, but that
- 9 was combined with other data that you saw, but you're not
- 10 allowed to divulge it.
- 11 ACTING DEP. DIRECTOR PALMER: Right. And
- 12 there's a lot of overlap. And there's a lot of good work
- 13 I'm sure that has been done. But from at least at this
- 14 point, without looking into it further I'd say, "Then
- 15 provide us that information or a summary." You know,
- 16 "Point, give us more." We're not expecting to do the
- 17 whole.
- 18 PANEL MEMBER LINARD: Well, that's been a
- 19 problem from day one is because some of that information
- 20 isn't yours to give out.
- 21 ACTING DEP. DIRECTOR PALMER: Okay, understood.
- 22 PANEL MEMBER COHEN-HUBAL: It is a challenge
- 23 for ECA definitely.
- 24 PANEL MEMBER LINARD: And it's a challenge for
- 25 EPA too. The data is there and they can't get it. And

- 1 they don't want to make -- just accept ECA's opinion
- 2 carte blanche.
- 3 PANEL MEMBER COHEN-HUBAL: Although EPA does
- 4 similar things too sometimes.
- 5 PANEL CO-CHAIR MORAN: Yeah.
- 6 PANEL MEMBER LINARD: We know.
- 7 PANEL MEMBER COHEN-HUBAL: Just saying. We're
- 8 all --
- 9 ACTING DIRECTOR WILLIAMS: But EPA is going to
- 10 share so much under TSCA since their new state CBI
- 11 sharing provisions, right? (Laughter.) I wonder why
- 12 everyone's laughing?
- 13 PANEL CO-CHAIR MORAN: So, a new topic, are
- 14 there other questions that staff have for the panel?
- 15 We've talked about a bunch of things. But there are
- 16 other things that people have raised and just we want to
- 17 speak up.
- 18 MS. ROMERO-FISHBACK: I had a quick question.
- 19 ACTING DIRECTOR WILLIAMS: You need to say your name.
- 20 (Overlapping colloquy.)
- 21 ACTING DEP. DIRECTOR PALMER: Yeah, Come up
- 22 here.
- 23 MS. ROMERO-FISHBACK: Okay. Sorry, I didn't --
- 24 my name is Michelle. And I had a question for Dr.
- 25 Whittaker, because I felt your work is really

- 1 fascinating. And my question, excuse me, goes towards
- 2 how do you handle the data gaps on your AAs? And how do
- 3 you, if you were to do it quantitatively, how do you
- 4 compare it or if there is any comparison with
- 5 uncertainty? Because I'm aware for like risk assessment
- 6 you can put in with certain factors, you can multiply,
- 7 you can do some sort of quantitatively.
- 8 But for AAs it's just sort of been lingering in
- 9 my mind like well, you have a data gap. And maybe some
- 10 of those smaller companies may not have access to like
- 11 some sort of sophisticated modeling. Or maybe they don't
- 12 even have contrasting studies or something that they can
- 13 pull off. How would you, in your experience, have
- 14 managed that?
- DR. WHITTAKER: Well, we follow -- OECD has
- 16 really good guidelines on how to address data gaps and we
- 17 use a combination of approaches. So now it's called NAMS
- 18 now. So sometimes someone will be doing Read-Across or
- 19 they'll hire a consultant to just do -- a lot of people
- 20 don't know how to use QSAR Toolbox, because it really is
- 21 not user-friendly. Not to scare you. If you're going to
- 22 use it you should try and get, I would recommend, funding
- 23 to get to Barcelona for a 40-hour course. And you will
- 24 leave knowing how to use it. It's tough, but it's -- so
- 25 you'll use it.

- 1 The person should be using a combination of
- 2 approaches. And what I like to see is I'll use a couple
- 3 of different models and a couple of different approaches.
- 4 And I'll look for consistency.
- 5 Almost any endpoint can be addressed using a
- 6 combination of techniques. It's very unusual now where
- 7 someone just says, "I guess I don't know." Yeah, there's
- 8 uncertainty. And if you're pulling from that a very
- 9 close surrogate and you can -- there are techniques.
- 10 Toolbox has it for example where it's called the Tanimoto
- 11 coefficient to look at structural similarity. And once
- 12 you learn how to use those tools it's not perfect, but
- 13 you can pull a chemist in who will laugh. I mean, I'll
- 14 say, "This is a close surrogate. The QSAR Model, it just
- 15 tells me so." Me and Jen Tennaro (phonetic) will start
- 16 laughing. She'll say, "Go back and pick up your
- 17 chemistry book. You're so wrong."
- 18 So it's really a lot of judgment and you just
- 19 have to -- you know, the people submitting to you should
- 20 be transparent. And they're obviously going to try and
- 21 advocate that it's a strong surrogate. But if you see
- 22 lots of data gaps and they say, "Well, we just don't know
- 23 if something is reproductively or developmentally toxic,"
- 24 there are really tools out there that -- they're not
- 25 perfect, but it's a good start. And I think they just

- 1 have to be -- you have to be transparent with them and
- 2 say, "Well, go back to the drawing board."
- 3 Like I review MCPs for Oregon and those are
- 4 contaminants that are contained in children's products.
- 5 And it was normal initially to say, "Well, can you go
- 6 back and just look at that a little bit more?" and "Are
- 7 you sure? Did you look at that?" Or "Here are some
- 8 tools you can use." Most people just aren't familiar
- 9 with the tools. And so it was normal initially to have
- 10 some iterations with submitters who would just not know
- 11 how to address certain endpoints.
- 12 It was very unusual if someone comes in and
- 13 they say, "We've addressed every single endpoint in that
- 14 checklist for you. And it's perfect." I would really be
- 15 impressed and wonder is that really true. So you will
- 16 see some.
- 17 And then they'll think that if they don't talk
- 18 about it that it's not a data gap. That's another funny
- 19 thing I see all the time. That's like the beauty of when
- 20 Design for the Environment created the famous benchmark
- 21 table that we've all borrowed from. And it really lays
- 22 bare, which endpoints aren't addressed. Still not super-
- 23 strong on -- I got tell you, as Kelly will say, "On
- 24 certain environmental endpoints." But those are harder
- 25 admittedly. You're not going to know if something is

- 1 going to hurt a honeybee versus a bumblebee often.
- 2 But you're dealing with methylene chloride
- 3 that's a carcinogen. And the alternatives are most
- 4 likely going to have a data set that will address the
- 5 standard hazard endpoints.
- I don't know, Kelly, if you have some other
- 7 input on that. But for a lot of the standard hazard
- 8 endpoints I feel fairly comfortable with the NAM
- 9 technologies, or techniques rather, that exist to address
- 10 those endpoints. It's not perfect though.
- 11 PANEL CO-CHAIR MORAN: Yeah, see I don't have -
- 12 I've been looking into it but I'm not going to claim
- 13 I'm an expert in any of the predictive methods. What
- 14 I've been watching is that EPA's Pesticides Office is
- 15 using the predictive methods to fill data gaps in
- 16 environmental fate and chemistry. And they've been doing
- 17 that for quite a while now, so that they at least have a
- 18 sense of where does this fall?
- 19 They are starting to use the predictive methods
- 20 for aquatic predictions at QSAR and that's -- they're
- 21 confident enough to be using it. I think the agency
- 22 really needs to make its independent judgment there. And
- 23 I know that you all have been looking into these methods
- 24 or having conversations about them. And I'm very
- 25 intrigued by what Meg has to say about this. I don't

- 1 know if others want to weigh in on that particular
- 2 question. This is a hard question.
- 3 MS. ROMERO-FISHBACK: Oh.
- 4 PANEL CO-CHAIR MORAN: Yeah, this is a good
- 5 question.
- 6 MS. ROMERO-FISHBACK: Thank you.
- 7 DR. WHITTAKER: And I think for some tests,
- 8 testing the whole formulation like a biodegradation test,
- 9 the test methods that are out there aren't super-
- 10 expensive to do. So if someone wants to say, "I've got a
- 11 mixture. And this is I've got a paint-stripper
- 12 formulation," they can run and go do the actual
- 13 biodegradation tests and run to a laboratory that can do
- 14 that to address those types of questions fairly without
- 15 breaking their bank.
- Once they get to, "Well, this is really the
- 17 alternative we want," they are not going to run, most
- 18 people won't run and test 20 things at a testing lab.
- 19 But once they get to the point of, "This really looks
- 20 good" then that's when I've seen clients go and they go
- 21 to a lab and they'll have those tests run. And then
- 22 ideally demonstrate "Wow, this is a really good mixture
- 23 or chemical or formulation. And we can demonstrate that
- 24 it's going to biodegrade and it's not aquatically toxic,
- 25 you know, different trophic levels." But most people

- 1 want to do that after they are pretty confident, so they
- 2 don't waste the money.
- 3 PANEL CO-CHAIR MORAN: So other questions that
- 4 the staff have?
- 5 DR. WHITTAKER: That's a hot seat. (Laughter.
- 6 MS. GRANT: Thanks.
- 7 PANEL CO-CHAIR MORAN: Yes. It's a hot day.
- 8 MS. GRANT: I'm Kelly Grant. And Meg, I kind
- 9 of wanted to follow up with you in terms of our
- 10 regulations don't allow us to -- oh, sorry -- don't
- 11 require the REs to generate new data. How does that fit
- 12 in with modeling and NAMS data that aren't so onerous to
- 13 generate, but might still be considered new data?
- DR. WHITTAKER: Oh, interesting if it's new
- 15 data. Hmm.
- 16 Well, NAMS will be an important part of helping
- 17 the submitter answer the question of is something safer?
- 18 And it shouldn't break their bank to use free models.
- 19 You're not saying they have to use DEREK, which costs an
- 20 arm and a leg to make a prediction. So I don't think
- 21 you're going to get too much feedback from the use of
- 22 free models. And would that be considered new data?
- 23 PANEL CO-CHAIR MORAN: Yeah.
- 24 DR. WHITTAKER: That's a good question.
- 25 PANEL MEMBER COHEN-HUBAL: You know, see, I

- 1 think it's really an odd thing when model output is
- 2 considered data. I mean, I don't know. My background is
- 3 engineering and modeling. And I just don't -- we post to
- 4 the Chemistry Dashboard exposure data, which is modeled
- 5 with a -- they are using the term commonly modeled data,
- 6 but it's not. It's modeled output. There's parameters,
- 7 some of the parameters -- even some of the parameters are
- 8 wrong. So I just hope your program doesn't have to call
- 9 model output "new data." That would be discouraging.
- 10 PANEL CO-CHAIR MORAN: So your advice is -- and
- 11 I think that's a common experience.
- 12 PANEL MEMBER COHEN-HUBAL: My advice is that
- 13 data -- and my advice is that if you're not measuring it
- 14 -- I'm not saying it's not information. Modeling is a
- 15 really important way of using available information and
- 16 understanding of physics and chemistry and other
- 17 behaviors and principles to take whatever measured
- 18 information is out there and interpret and use it and
- 19 extrapolate it and extend it. But I just, and maybe I
- 20 don't know, maybe I'm just wrong, but to me model output
- 21 is not new data.
- 22 ACTING DEP. DIRECTOR PALMER: Just a comment we
- 23 don't require people generate new data, but people can.
- 24 PANEL MEMBER COHEN-HUBAL: Right.
- 25 ACTING DEP. DIRECTOR PALMER: And I think that

- 1 the tradeoff that the responsible entities are going to
- 2 have to evaluate, particularly for something that's low-
- 3 cost and easy to do, is if you choose not to do that then
- 4 you're throwing yourself on the mercy of our discretion
- 5 and understanding.
- 6 PANEL MEMBER COHEN-HUBAL: That's right.
- 7 ACTING DEP. DIRECTOR PALMER: And that's, I
- 8 would argue, probably not the best approach to tell your
- 9 story.
- 10 PANEL CO-CHAIR MORAN: So that's a good example
- 11 of one of the ways that EPA is using it's predict tools
- 12 is to justify saying, "Well we could use this number," or
- 13 "You could get a better number and we can make a better
- 14 decision." So oftentimes the number they will propose to
- 15 use is pretty conservative, so the risk would be higher.
- 16 And so they are basically encouraging manufacturers to
- 17 invest in the testing. So while you're not requiring it,
- 18 that your approach to how you're filling the gaps
- 19 actually makes a difference.
- 20 And always it's "Does this matter? Is this the
- 21 most important thing for decision making? Is it really
- 22 the thing that's going to change where you're headed?"
- 23 So other questions from staff?
- 24 MS. GROSS: I don't think I need to go to the
- 25 table, but --

- 1 (Off mic colloquy.)
- 2 PANEL CO-CHAIR MORAN: Sorry, I think Meg, is
- 3 that up again?
- 4 DR. WHITTAKER: Oh, well it'll wait and then
- 5 I'll help you (indiscernible)
- 6 PANEL CO-CHAIR MORAN: Okay, oh sorry. I
- 7 missed that.
- 8 MS. GROSS: One of the things that I can just
- 9 list --
- 10 ACTING DIRECTOR WILLIAMS: And you are --
- MS. GROSS: I'm Anna Gross, sorry.
- 12 PANEL CO-CHAIR MORAN: Welcome, Anna. Thank
- 13 you.
- MS. GROSS: One of the things I think is
- 15 supposed to kind of define this program is like really
- 16 this emphasis on life cycle thinking. And I think a lot
- 17 of this discussion seems to be kind of a comparative risk
- 18 assessment that we're kind of envisioning and talking
- 19 about. And I don't think that's exactly it. And I am
- 20 concerned as someone who is not super-familiar with the
- 21 rest of the life cycle analysis part of it, you know, not
- 22 giving too much weight to one sector of the type of
- 23 analysis that we're most familiar with and that we will
- 24 likely have data even if there are data gaps there.
- 25 There's this whole other sector of emissions and the

- 1 whole rest of the supply chain that companies might,
- 2 probably don't have access to a lot of that data and
- 3 won't be able to provide.
- And how are we not just -- you know, it's one
- 5 thing to have a regrettable substitute that has similar
- 6 toxicological properties and is chemically similar. And
- 7 you can say like "Don't use certain BPA alternatives,
- 8 because they're similar." But it's another thing if
- 9 something is lighting up a whole other sector of the life
- 10 cycle, how do we look out for that? That's my question.
- 11 PANEL CO-CHAIR MORAN: I'm wishing Julie
- 12 (phonetic) were here. Meg, are you on this or can we
- 13 hold out for a minute?
- DR. WHITTAKER: Oh, I can hold out. Oh, yeah.
- 15 I just had another one issue that is about the last.
- 16 PANEL CO-CHAIR MORAN: We'll come back, and my
- 17 apologies. Ann looks like she wants to weigh in here.
- PANEL MEMBER BLAKE: I'm my formulating my
- 19 thoughts on the fly like you have. That's a very tricky
- 20 one and it's another like functional use, it's going to
- 21 be tricky to think about in the abstract. But I think --
- 22 where do I go from here?
- 23 When you look at a set of alternatives I
- 24 suspect that they'll fall into not more than two or three
- 25 clusters of the way people are approaching the same

- 1 challenge. And they will light up the same part of the
- 2 supply chain. I don't know how you look out for it,
- 3 except just I think go back to our recommendation earlier
- 4 that many of us repeated, to get to know the product
- 5 category really well. And look at the alternatives and
- 6 where they're likely to light up the supply chain.
- 7 So I'm thinking about alternatives to bleach
- 8 for example that we said that they were safer for their
- 9 application. And then found out that it lit up a totally
- 10 different part of the supply chain. We didn't know that
- 11 initially when we redid that analysis.
- 12 So I appreciate your concern. I'm really
- 13 encouraged that you're thinking about that already. I
- 14 think that that's already, that mindset, is opening you
- 15 up to looking for it, so you probably will. You're
- 16 probably better prepared to find that hot spot elsewhere
- 17 in this project. And you've also got an multi-
- 18 disciplinary team, so you're going to have other folks
- 19 with input on where that might happen.
- MS. GROSS: All right.
- 21 PANEL CO-CHAIR MORAN: This is a really good
- 22 question.
- 23 Meredith, Elaine, and we're coming back to Meg
- 24 later.
- 25 ACTING DIRECTOR WILLIAMS: So I cannot believe

- 1 you didn't just immediately say "conceptual model." What
- 2 is the world coming to?
- 3 So I mean we've had a lot of discussion that
- 4 you have of course not been privy to about the importance
- 5 of using conceptual models to really map out the
- 6 differences and to help with the identification of the
- 7 relevant factors for each of the alternatives. And this
- 8 is where I think it's one way to get to those
- 9 differentiators and the differential factors.
- 10 MS. GROSS: Right. But how -- so some of the
- 11 relevant factors like I think we all on our team kind of
- 12 have some questions about the relevant factors, because
- 13 sometimes you can't know a factor is relevant until you
- 14 look at it more closely. And so it might be hard to
- 15 screen out exactly what's relevant. And if we're not
- 16 that's -- yeah.
- 17 PANEL CO-CHAIR MORAN: Yeah. That's it. I
- 18 think Meredith -- she's kind of pointing at me, because
- 19 I've been talking a lot about conceptual models. And I
- 20 had wished that the regs required conceptual models,
- 21 because they're so important for the picture. And what
- 22 you're getting at is actually part of what I'm getting at
- 23 when I say what's missing? That that's the hardest part
- 24 of the review, so your question is so on point, because
- 25 you're having to say it's very common for people to be

- 1 missing important parts in the life cycle thinking.
- 2 Because they are so focused on doing things that are the
- 3 kinds of things we're talking about.
- 4 So that's why I'm actually super-glad you came
- 5 to the table and brought this to the conversation. I
- 6 don't think we're going to have perfect -- we don't have
- 7 perfect answers but trying to pull that thread and what
- 8 is going on in each of these areas? And I know you all
- 9 are doing your homework and thinking about the
- 10 alternatives now, so you have probably have already
- 11 thought about it and recognized that some alternatives
- 12 are going to light up some additional things.
- 13 And getting the relevant factors will tell you
- 14 there's some different relevant factors for these kinds
- 15 of alternatives, because of the life cycle thinking that
- 16 we're doing. That's the endgame. I wish I could tell
- 17 you something better than that.
- 18 PANEL MEMBER BLAKE: So can I add to that?
- 19 PANEL CO-CHAIR MORAN: So quickly and then
- 20 Elaine.
- 21 PANEL MEMBER BLAKE: Yes. Yeah. Just keep in
- 22 mind it's going to be an iterative process, so you don't
- 23 have to get it right the first time.
- MS. GROSS: Right.
- 25 PANEL CO-CHAIR MORAN: Yeah.

- 1 PANEL MEMBER COHEN-HUBAL: So I, of course, was
- 2 going to say, conceptual model problem formulation.
- 3 But I think the other point that may be worth
- 4 just sort of thinking about is because economics is a
- 5 piece of this too, is that many of the upstream factors,
- 6 upstream to the manufacture of the alternative or to
- 7 sourcing the alternative or something, I don't think
- $8\,$ that's the major contribution of this program. And I
- 9 could be wrong, but to me some of those things come out
- 10 in the economics, that if something is going to require
- 11 more resources to produce that there's not going to be
- 12 the incentive for the manufacturer to make that
- 13 alternative choice.
- But the downstream, including all the way to
- 15 disposal, recycling, disposal and stuff, I think those
- 16 are going to be really places where this program
- 17 contributes a lot. And where there isn't any economic
- 18 drivers there's less economic drivers right now for
- 19 addressing those issues around product safety. So I do
- 20 think it's okay for the program to -- I don't know in the
- 21 regs what's okay, but in my mind in terms of the sort of
- 22 goals of the program I think it would be okay to sort of
- 23 if there's a submission and they've kind of laid out that
- 24 conceptually these are the steps, but here's the ones
- 25 that matter the most or for the comparison that this

- 1 program should be evaluating, I think it won't seem as
- 2 intractable as well how do you compare everything to
- 3 everything?
- 4 PANEL CO-CHAIR MORAN: But a good example of
- 5 this is just in the methylene chloride context. So
- 6 methylene chloride stripper, if you have leftover
- 7 solution it's a hazardous waste. But if it's an aqueous-
- $8\,$ based stripper you might want to pour it down the drain
- 9 even if you've stripped a lead-contained paint.
- 10 PANEL MEMBER COHEN-HUBAL: Right. And that's
- 11 all downstream --
- 12 PANEL CO-CHAIR MORAN: -- and you've got the
- 13 lead in there.
- 14 PANEL MEMBER COHEN-HUBAL: -- of use. So
- 15 that's really important, I think, for this program.
- 16 PANEL CO-CHAIR MORAN: Yeah. And that's an
- 17 example of what you're thinking about. So then we're
- 18 bringing a whole new set of things. And that's why the
- 19 conceptual model is important, because you're thinking
- 20 through all of those various pathways. But that brings
- 21 in a new endpoint. Now you're actually taking something
- 22 from the product and you're putting it into a new medium.
- 23 So that's a hard one.
- I don't think you're going to be perfect on
- 25 this stuff the first time you review AAs. But I think

- 1 that you guys have the capacity to see way more than the
- 2 little tiny example I just gave you.
- 3 MS. GROSS: Okay.
- 4 PANEL CO-CHAIR MORAN: So Meg's very patiently
- 5 waiting. Sorry about that.
- 6 DR. WHITTAKER: It would be really neat if DTSC
- 7 would consider co-hosting a Sustainable Futures Workshop.
- 8 It's a lot easier to teach people how to use some of the
- 9 easier predictive models than life cycle assessment. You
- 10 can't teach, in my opinion, life cycle or even thinking,
- 11 intense thinking, in a two-day workshop. And I know EPA
- 12 was looking for sponsors. And most of my staff and I
- 13 have taken it. And by the time you leave you'll know how
- 14 to use it. You'll know how to make sure you've got your
- 15 logKOW, which is really important for predicting aquatic
- 16 toxicity or bio-concentration -- or biodegradation,
- 17 excuse me.
- 18 And I don't think -- I'm sure it sounds like
- 19 you're best buds with all the people at EPA, so it's
- 20 (indiscernible) I believe it's Cynthia McOliver now,
- 21 Kelly Mayo Bean left, but that would be really neat.
- 22 And the people who have to give you AAs, they
- 23 haven't had a training for a couple of years, would
- 24 benefit from the training and give you a better quality
- 25 product, so that you don't have to say, "Well, you've

- 1 modeled all those, but you've left out -- you have to
- 2 input logKOW or these are not reliable predictions." So
- 3 you'll get a better-quality work product, so it'd be
- 4 worth the investment in my opinion. I've enjoyed the
- 5 training.
- 6 PANEL MEMBER COHEN-HUBAL: Are you going to
- 7 post all these training recommendations?
- 8 DR. WHITTAKER: No, I don't want to get in
- 9 trouble, so but these other ones are really good too.
- 10 But I think the Sustainable Futures is nice.
- 11 PANEL CO-CHAIR MORAN: All right. So I want to
- 12 go back to Tony and Xiaoying and just see if there's
- 13 anything else. We've got a couple of minutes left.
- 14 There's one more question I want to ask before we close
- 15 and just see is there anything else here that you want to
- 16 say or ask?
- MR. LUAN: Oh, I don't have any. Does anybody
- 18 else have any? No.
- 19 PANEL CO-CHAIR MORAN: All right. So the one -
- 20 thank you and thank everybody on this.
- I wanted to circle back around to the metrics
- 22 thing. So Art raised something this morning about the
- 23 economic benefits to the state of this program. And I
- 24 just wanted to check in. We were yesterday kind of
- 25 brainstorming a little bit of the other ancillary

- 1 benefits and impacts in the program. And that was
- 2 something that hadn't come up. But then Art raised it
- 3 this morning, so I just wanted to see if anybody had any
- 4 thoughts about that. I don't know if there's a metric
- 5 that goes with that.
- 6 All right, Ann?
- 7 PANEL MEMBER BLAKE: So we've been talking in
- 8 other context about quantifying health costs and health
- 9 impacts, so this is a very live conversation. And I'm
- 10 happy to talk about that further, but it's very much in
- 11 flux.
- 12 So how do we start pending the economic costs
- 13 of health? And then as we've talked about yesterday,
- 14 it's really hard to allocate prevention to that outcome.
- 15 But anyway, at least indicate these -- this is what our -
- 16 the status quo of what it was costing us with specific
- 17 chemical exposures. And then saying and somehow figuring
- 18 out how this program is impacting that.
- 19 Because one of the things that we have not, we
- 20 collectively as a society have not articulated well -- as
- 21 you all know I'm preaching to the choir here -- is that
- 22 we have not articulated the externalized costs of the
- 23 status quo now and the health and the environmental
- 24 impacts and because those are hard to measure. So I mean
- 25 I would love to work with the economists that you've

- 1 hired as well to figure out better metrics on that. But
- 2 that's one approach to think about this, is quantifying
- 3 health benefits.
- 4 PANEL CO-CHAIR MORAN: Well, I'm also thinking
- 5 about the stimulating innovation and creating market
- 6 opportunities.
- 7 PANEL MEMBER BLAKE: Absolutely, yes.
- 8 PANEL CO-CHAIR MORAN: Or actually advantaging
- 9 companies in California who are serving a California
- 10 market.
- 11 PANEL MEMBER BLAKE: Yeah. Yeah, both sides to
- 12 that, yes.
- 13 ACTING DIRECTOR WILLIAMS: I kind of wanted to
- 14 ask Ann, are you talking about willingness to pay? Or
- 15 are you thinking specifically about -- I mean, is that
- 16 embedded in what you're saying?
- 17 PANEL MEMBER BLAKE: A willingness to pay? No.
- 18 ACTING DIRECTOR WILLIAMS: It isn't. Okay.
- 19 PANEL MEMBER BLAKE: No. It's quantifying what
- 20 is it costing us in the health sector.
- 21 ACTING DIRECTOR WILLIAMS: Okay, because people
- 22 are flipping that around more and more.
- 23 PANEL MEMBER BLAKE: I would like to have that
- 24 conversation.
- 25 PANEL CO-CHAIR MORAN: There's some costs are

- 1 easier than others, disposal costs are easier to deal
- 2 with than a lot of other things.
- 3 ACTING DIRECTOR WILLIAMS: You're right. But
- 4 the willingness to pay is, "How much are we willing to
- 5 pay to have a better health outcome?"
- 6 PANEL MEMBER BLAKE: I see.
- 7 ACTING DIRECTOR WILLIAMS: "To have a safer
- 8 product, to have a better environment." And when you ask
- 9 people questions in those ways you get to different
- 10 answers. And you actually can monetize that way, so
- 11 another area where Tracey Woodruff has been active.
- 12 PANEL MEMBER BLAKE: Yeah.
- 13 PANEL CO-CHAIR MORAN: Do you want to say
- 14 something, Elaine?
- 15 PANEL MEMBER COHEN-HUBAL: So we do have
- 16 examples where some of these things, you know, the health
- 17 benefit and costs for air pollution reduction. I mean,
- 18 air pollution is always on of these things where they're
- 19 so much easier to do. So that's a good place to draw
- 20 examples. I know we had one recently where that was
- 21 done. There's a couple of tools, and I'm blanking on
- 22 them now, at EPA where they've done some of that kind of
- 23 analysis. But everything's easier on air pollution, is
- 24 all I've get to say.
- 25 PANEL CO-CHAIR MORAN: So if nothing else, if

- 1 there are ever a case study example comes forth, that
- 2 that is something it seems that would be part of the
- 3 conversation around the success of the program.
- 4 MR. LUAN: Can I get that?
- 5 PANEL CO-CHAIR MORAN: Yes, okay.
- 6 ACTING DEP. DIRECTOR PALMER: I think yeah, we
- 7 had -- I can't remember when, but the last time we had an
- $8\,\,$ expert from EPA on monetizing air, the cost of air
- 9 pollution and pesticide issues was quite interesting.
- $10\,$ And so I'm wondering if we have this desire and need to
- 11 monetize some impacts?
- On the other end of the spectrum we'd like to
- 13 be looking at how we can influence innovation. And so it
- 14 might be timely to get, perhaps, Marty Mulvihill or
- 15 someone back to talk to us about the markets and our
- 16 decision making. And what factors are employed by people
- 17 who make the decisions in developing products. And maybe
- 18 some of you have thoughts about that.
- 19 But back to the shadow vs. shape, we're a small
- 20 group. We can't change the world overnight, but I think
- 21 this concept of expanding people's view, using the market
- 22 as a tool for positive change is something that we'd be
- 23 curious about, too.
- 24 PANEL MEMBER COHEN-HUBAL: Me too. And for me
- 25 that kind of goes back also to just whether it's

- 1 innovation or even businesses just using their success in
- 2 the program as a marketing tool. Or as in their own
- 3 bookkeeping on like sort of some of these ESG indicators
- 4 where that starts to show up, that chemicals and safety
- 5 of products beyond the current indicators, which are
- 6 mostly focused on resource use and impacts on those ends.
- 7 But that kind of thing, again I don't know how that would
- $8\,$ be tracked or whether that'll be something that happens.
- 9 But it would be a way of at least showing that the
- 10 business, that this program has influenced how businesses
- 11 think about that as having value.
- 12 PANEL CO-CHAIR MORAN: All right. So we've
- 13 reached the witching hour, 11:45 a.m. And it's time for
- 14 us to wrap up the meeting. We've covered a pretty full
- 15 array of topics in pretty rapid-fire fashion. It was, I
- 16 thought, a pretty amazing discussion the last couple
- 17 days. And you guys are probably as mentally tired as I
- 18 am at this point. So I wanted to move into the
- 19 opportunity to close this.
- I know rather than attempt to reiterate all the
- 21 highlights of everything we've said I'll remind everyone
- 22 that the staff have been taking copious notes. There's
- 23 actually a recording and a transcript being generated
- 24 from the meeting. So there's lots of different ways that
- 25 folks will be able to access the conversation and what we

- 1 did.
- 2 And again I encourage the staff if there's
- 3 specific questions like means and references and things
- 4 like that the panelists have, I think, been quite willing
- 5 to, and are allowed to individually interact with the
- 6 staff to follow up on any of those items, so I'd
- 7 encourage panelists to be responsive if the staff reach
- 8 out.
- 9 And particularly on this last question, it's a
- 10 pretty short time before they're going to start getting
- 11 the AAs. So don't be surprised if you get some
- 12 questions. And I think and I'm pretty confident that the
- 13 folks in the room and the folks not in the room will be
- 14 very happy to help out the staff. So I just want to
- 15 reiterate that to the staff team that we're your science
- 16 advisors at the meeting. But individually if staff have
- 17 questions that are appropriate to ask a science advisor.
- 18 It is the role of the science advisor panel to provide
- 19 information to support the team.
- 20 But personally, I've got to say the discussion
- 21 here has increased my confidence that the staff is
- 22 prepared to handle these things. And I know we've had
- 23 many discussions where the science advisory panel acts as
- 24 if we're saying new things. And it was all the stuff
- 25 that the staff already knew ahead and had already been

- 1 thinking about. But this one in particular really made
- 2 me feel like that the staff had really done their
- 3 homework. And the fact you're asking this, the good
- 4 questions, and then we're responding with things you've
- 5 already been working towards managing just gives me tons
- 6 of confidence that you're ready for those July
- 7 submittals.
- 8 So before we go to the final closing remarks
- 9 from Art and me, I'd like to offer Meredith a chance to
- 10 say a few words here.
- 11 ACTING DIRECTOR WILLIAMS: Well, we'll start
- 12 with a round of thank yous. Today is Admin Professionals
- 13 Day and they are not in the room, our administrative
- 14 professionals who (indiscernible). I think we would be
- 15 remiss if we didn't take a second or a minute to just
- 16 appreciate how much they've done with the logistics in
- 17 making the trains run on time, and just arranging
- 18 everything. And I used to be very hands-on. And now I
- 19 just have no idea what's going on and yet everything
- 20 works out just fine, so that really speaks to staff. And
- 21 it speaks to the admin team in particular.
- I do want to thank staff for really picking up
- 23 the ball and running with it this meeting. And Anne
- 24 Cooper, you've really helped coordinate a lot of the
- 25 internal discussion of staff about the concepts that we

- 1 put forth and discussed. And we're just flat-out proud
- 2 of the work that was done by staff to do all the thinking
- 3 to get us to this conversation.
- I know you are all tired, however, I wish we
- 5 could keep going. (Laughter.) That's just me. When
- 6 Kelly said, "Oh, I'm so glad you can make the time," I'm
- 7 like, "Oh, a vacation." So I just enjoy these meetings
- 8 so much. I'm already looking forward to the next one to
- 9 be honest. My mind is thinking of ideas and I'm really
- 10 excited about it.
- I will tell you we have made a commitment to do
- 12 a Prioritization Lookback at the next meeting, in the
- 13 fall meeting. Based on the Green Chemistry Report, we're
- 14 going to take a look at -- by that time we'll have quite
- 15 a number of products under our belt in terms of having
- 16 proposed them and we'll talk about some of the approaches
- 17 we've used and what we've learned. And where we think
- 18 the opportunities are to do double-down on certain things
- 19 and to tweak our processes. And we'll give you a window
- 20 into some of that activity. And I'm really looking
- 21 forward to that discussion.
- 22 And as always, just thank you for the guidance.
- 23 Again, as Karl indicated when he gave you the program
- 24 update, we feel as though we're up another step up in
- 25 terms of the quality of the program, the productivity of

- 1 the program, the strength of the staff, you name it.
- 2 And that wouldn't possible -- not only for your
- 3 broad science advising and the wealth of experience, but
- 4 also for your cheerleading. And you're cheerleading not
- 5 just in the room, but as you're out in the world talking
- 6 to people about the program, as you talk to other folks
- 7 in government who may wonder what are those SCP people up
- 8 to?
- 9 I'm just very grateful for that continued
- 10 support, so thank you all for getting here, for staying
- 11 funded and the continued dedication to what we're trying
- 12 to do here.
- 13 And our co-chairs in particular are just so
- 14 steady at the helm, brought us to another good place in
- 15 terms of challenges. It's very funny now, because
- 16 sometimes Anne Cooper and I bring a topic forth and we
- 17 go, "Well, we thought that was going to go better." But
- 18 we always end up in a good place. And that's because you
- 19 are so thoughtful in your feedback to us to shape these
- 20 meetings, so thank you.
- 21 PANEL CO-CHAIR FONG: And so let me just point
- 22 out one of the reasons why these meetings go so well, and
- 23 we get so much out of it, it's because of the tremendous
- 24 amount of hard work that Anne Cooper and the staff put
- 25 into preparation. It's just amazing. So I think it

- 1 should be obvious from the materials that you've received
- 2 prior to the meeting how much work goes into the
- 3 preparations.
- 4 So, Anne Cooper. (Applause.)
- MS. COOPER DOHERTY: Well, it's thanks to the
- 6 team that's helping me, Kelly and (indiscernible)
- 7 PANEL CO-CHAIR FONG: Yeah, could you guys
- 8 stand up please?
- 9 MS. COOPER DOHERTY: Two of them are here. You two,
- 10 come up. Just at least wave. (Applause.) And
- 11 especially Anna and (indiscernible) they all helped put
- 12 together this.
- 13 ACTING DEP. DIRECTOR PALMER: And just a shout-out
- 14 to Baoku, who makes it all work here on the technical
- 15 side of it. We've been in this building since 2001. And
- 16 we continue to have challenges in this world, but Baoku
- 17 makes it all work, so thank you. (Applause.)
- 18 PANEL CO-CHAIR MORAN: So and I wanted to just,
- 19 again, thank everyone here. The panel members were very
- 20 prepared. I think your comments were really well
- 21 informed by a lot of thinking and staying on top of and
- 22 tracking the program, so your experience here as well as
- 23 your preparation for the meeting. And I jointly want to
- 24 be thanking the staff.
- Today's Earth Day.

- 1 ACTING DIRECTOR WILLIAMS: It's Earth Day here. It
- 2 was Earth Day two days ago everywhere else.
- 3 PANEL CO-CHAIR MORAN: It's Earth Day in California
- 4 today.
- 5 ACTING DEP. DIRECTOR PALMER: Every day is Earth
- 6 Day.
- 7 PANEL CO-CHAIR MORAN: and I can't think of a better
- $8\,$ way to spend Earth Day than working to make safer
- 9 consumer products. And people joke about Earth Day is
- 10 every day, but for the folks who are here, the folks in
- 11 the room and the staff who are working on this, every day
- 12 is Earth Day.
- What you're going really matters. It's really,
- 14 really important for our state, for our country. And I
- 15 thank you for doing that. I thank you for your
- 16 dedication, I thank you for your quality. I thank you
- 17 for bringing science to this program and we're behind
- 18 you. We'll be supporting you through all the next steps
- 19 in this journey. So thank you very much. This meeting
- 20 is adjourned.
- 21 (The meeting of the Green Ribbon Science Panel
- concluded at 11:54 a.m.)

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REPORTER'S CERTIFICATE

I do hereby certify that the testimony in the foregoing hearing was taken at the time and

place therein stated; that the testimony of said witnesses were reported by me, a certified electronic court reporter and a disinterested person, and was under my supervision thereafter transcribed into typewriting.

And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.

IN WITNESS WHEREOF, I have hereunto set my hand this 24th day of May, 2019.

PETER PETTY CER**D-493 Notary Public

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I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were transcribed by me, a certified transcriber and a disinterested person, and was under my supervision thereafter transcribed into typewriting.

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122

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